IN THE COURT OF COMMISIONER OF PATENTS
FOR THE REPUBLIC OF SOUTH AFRICA
(PRETORIA)

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

13/7/2026
DATE

SIGNATURE

CASE NO: 2025-008723

In the matter between:

ASTELLAS PHARMA INC.	**First Plaintiff**
ASTELLAS PHARMA (PTY) LTD	**Second Plaintiff**
and	
CIPLA MEDPRO (PTY) LTD	**Defendant**

Neutral Citation:

Delivered: By transmission to the parties via email and uploading onto CaseLines

the Judgment is deemed to be delivered.

JUDGMENT

SENYATSI J

INTRODUCTION

[1] This is a patent infringement action. The First Plaintiff, a Japanese company ("Astellas"), is the registered proprietor of South African Patent No. 2011/02406, entitled "Pharmaceutical Composition for Modified Release" ("the patent"). The second plaintiff is a registered licensee. The original patent was registered in Japan. The Defendant, Cipla Medpro (Pty) Ltd ("Cipla"), is a generic pharmaceutical company.

[2] Astellas alleged that Cipla's product, URTON, which contains the active pharmaceutical ingredient mirabegron, infringed claims 1 to 10 of the patent. Initially, Cipla defended the main claim, but following a series of admissions, the last of which was made on 8 May 2026, Cipla **conceded** that Astellas **had proven infringement**. Consequently, the only issue for determination is Cipla's counterclaim for the revocation of the patent.

[3] In its counterclaim, Cipla seeks revocation of the patent on three grounds:

(a) obviousness (lack of inventive step);

(b) insufficiency; and

(c) lack of clarity.

The resolution of these grounds depends fundamentally on the proper interpretation of claim 1 of the patent, specifically the meaning and effect of paragraphs [0013], [0014], and [0015] of the specification.

[4] Cipla contends that paragraph [0014] is a definition that must be read into claim 1, requiring a demonstrable, more-than-minimal reduction in a food effect, measured *in vivo*. The paragraph reads as follows:

On this interpretation, Cipla argues the patent is invalid for insufficiency and lack of clarity. Astellas, on the other hand, contends that paragraph [0014] is not a definition but merely provides examples of the reduction in food effect that will be achieved by a formulation meeting the dissolution profile of claim 1. On Astellas' interpretation, the validity of the patent stands or falls on the ground of obviousness.

[5] This judgment will first resolve the dispute over the interpretation of claim one (1). Thereafter, I will consider the grounds of invalidity advanced by Cipla in

light of the proper construction of the patent.

[6] During the oral submissions, the Plaintiff submitted correctly that any drug to be put in the market by the originator (patentee) or generic drug manufacturer, must **routinely** do the in vivo tests with the regulators.

GENERAL OBSERVATION ABOUT THE PATENT

[7] The patent was developed with the view to releasing the drug mirabegron with the modified food effect for dissolution for modifying long effect of dissolution thereof in dealing with the bladder related medical condition such that the dissolution takes place over a longer period after oral consumption with or without food.

THE INTERPRETATION DISPUTE

[7] The principles for interpreting patent specification are well-established. The court must ascertain, not what the inventor may have had in mind, but what the language used in the specification means, as it would be understood by a person skilled in the relevant art as well as the claims thereof.[1] The specification is addressed to persons skilled in the art, who are expected to

[1] See *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) at 614A-C and 613F-H

bring reasonable intelligence to bear upon its language, to make the best of it, and not to adopt an attitude of studied obtuseness.[2]

[8] In the present case, it is common cause that the skilled addressee is a skilled formulator. The question is whether such a person would understand paragraph [0014] as a binding definition or as a set of examples illustrating the therapeutic benefit of the claimed formulation.

[9] Paragraph [0013] states: "The term 'pharmaceutical composition for modified release' as used herein means a formulation … and the drug release is controlled to the extent that the effects by food are reduced." Paragraph [0014] then states: "The wording 'the effects by food are reduced' as used herein means, **for example**, a 10% reduction …". The words "for example" are crucial. They indicate that what follows is not exhaustive or mandatory definition, but an illustration of the kind of reduction that can be expected. This is the very antithesis of a definition clause. If the patentee had intended to

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[2] See *Roman Roller CC and Another v Speedmark Holdings (Pty) Ltd* 1996 (1) SA 405 (A) at 419D-E).

create a binding definition, it would not have used the permissive and illustrative phrase "for example."

[10] Furthermore, the patent's own examples and teachings confirm this interpretation. The specification explicitly states in paragraph [0007] that the inventors tested formulations with T80% values of 4, 6, and 10 hours and found that **all** could reduce the food effect. Paragraph [0015] then provides an *in vitro* dissolution profile (75% or less at 1.5 hours and at least 75% at 7 hours) as the characteristic of a "formulation in which the effects by food are reduced." This profile is now explicitly incorporated into claim 1 as integer I.

[11] A skilled formulator, reading the patent as a whole, would understand its core teaching to be this: a negative food effect associated with an immediate-release formulation of mirabegron can be reduced by formulating the drug as a modified-release composition that meets the specified dissolution profile, using the defined excipients. Paragraph [0014] merely provides examples of the degree of reduction that can be achieved. It does not impose a separate, binding *in vivo* test as an additional requirement of the claim. To hold otherwise would render the detailed *in vitro* dissolution profile in claim 1 superfluous, a result that contradicts the presumption against interpreting a

document in a way that renders parts of it meaningless. The UK judgment in *Astellas Pharma Industries Ltd v Teva Pharmaceutical Industries Ltd*[3] is persuasive on this point and aligns with this conclusion.

[12] Consequently, I find that paragraph [0014] is not a definition to be read into claim 1. The claim is to be interpreted as requiring the composition to meet the structural and dissolution rate requirements set out in integers A to J. The patent teaches that a formulation meeting these requirements will reduce the food effect. This is the invention.

OBVIOUSNESS (LACK OF INVENTIVE STEP)

[13] Cipla's primary attack on validity is based on obviousness, which it argues follows inevitably if its interpretation of claim 1 is rejected. The onus is on Cipla to establish, on a balance of probabilities, that the claimed invention was obvious to a person skilled in the art at the priority date (30 September 2008).

[14] The inventive step of the patent in suit is the provision of a modified-release formulation of mirabegron, comprising a specific hydrogel-forming polymer and a hydrophilic base, with a specific *in vitro* dissolution profile (75% or

[3] [2023] EWHC 2571 (Pat)

less at 1.5 hours and at least 75% at 7 hours), which has the effect of reducing the negative food effect observed with the immediate-release formulation.

[15] The state of the art relied upon by Cipla includes the "compound patent" (disclosing mirabegron for overactive bladder), the "preparation patent" (disclosing the OCAS hydrogel system for sustained release, particularly for drugs with short half-lives to enable once-daily dosing by targeting the colon), and publications by Fix, Michel, and Chapple (describing OCAS formulations for other drugs).

[16] The principles on inventive steps are trite. In terms of s 25(1) read with s 25(10) of the Act an invention must be one "which involves an inventive step".[4] This means that it must not have been obvious to a person skilled in the art of the patent, having regard to any matter which, immediately before the priority date of the invention, forms part of the state of the art.

[17] It is accepted in our law that obviousness is a factual question, the onus in respect of which rests with Cipla.[5] The issues which are to be determined as part of the enquiry into obviousness were set out in *Ausplow* as follows:

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[4] The Patents Act 57 of 1978, s25(1) & s25 (10) thereafter referred to as the "Act".
[5] *Ausplow v Northpark Trading ("Ausplow")* 2011 BIP 12 SCA para [45].

"(1) (a) identify the notional person skilled in the art; (b) identify the relevant common general knowledge of that person (i.e. the state of the art); (2) identify the inventive concept of the claim or if that cannot readily be done, construe it; (3) identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed; and (4) viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?" [6]

[18] I have carefully considered the evidence of the expert witnesses: Professor Walker for Cipla and Professors Davies and Dressman for Astellas. I found the evidence of Professors Davies and Dressman to be compelling, logically reasoned, and consistent with the contemporaneous common general knowledge. Professor Walker's evidence was, in several critical respects, less persuasive. His "de-linking" opinion that the food-effect independence of

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[6] Ausplow, para 34. The order in which the questions are considered is not important. In *Mantella Trading 310 (Pty) Ltd v Kusile Mining (Pty) Ltd 2015 BIP 1 (SCA) 44 to 46 and Sandvik Intellectual Property AB v Outokumpu Oyj* 2019 BIP 15 (SCA) para 12 considered these questions in the order in which they were set out in *Ensign-Bickford (South Africa) (Pty) Ltd and Others v AECI Explosives and Chemicals Ltd* 1999 (1) SA 70 (SCA) at 80H – J. I have swapped the order of questions (1) and (2) below.

OCAS observed in the prior art was not dependent on extended release into the colon was given without proper reasoning, was not contained in his expert summary, and was directly contradicted by the clear teachings of the prior art documents themselves. It appeared to be an opinion born of hindsight.

[19] The prior art, particularly the preparation patent and the Fix article, teaches that the OCAS system was designed to achieve drug release in the colon. This was to solve the problem of short half-life drugs, allowing them to be dosed once daily. The system was understood to be primarily suitable for drugs with high permeability, to allow for colonic absorption. Mirabegron, by contrast, has a long half-life (18-24 hours) and is poorly permeable (BCS Class 3). It also has poor solubility at the neutral pH of the small intestine and colon.

[20] A skilled formulator, tasked with solving a negative food effect for a drug like mirabegron, would have not been motivated to turn to a system designed for a different purpose (short half-life, once-daily dosing) and for drugs with different properties (high permeability). As Professor Davies explained, extending the release of a poorly permeable drug into the colon is counter-intuitive, as it would deliver the drug to a site where absorption is even less favoured. Extending the release of a drug with a long half-life is unnecessary

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and could raise safety concerns due to potential accumulation.

[21] The invention required the inventors to take a series of non-obvious steps. First, they had to decide to address the negative food effect through formulation, rather than simply instructing patients to take the drug on an empty stomach, which was a known and simpler alternative. Second, they had to conceive of using a modified release formulation to slow down the release of the drug, thereby "matching" the fed-state absorption profile derived from a deconvolution study. Third, they had to select a specific hydrogel-based technology (OCAS) but then adapt it for a purpose (targeting the small intestine, not the colon) and for a drug (long half-life, poor permeability) for which it was never intended. This was a creative and inventive application of a known technology, not an obvious combination.

[22] Furthermore, there was no evidence that any BCS Class 3 drug had been successfully formulated as an extended-release formulation by the priority date, nor that any formulation had been successfully developed to overcome a negative food effect associated with an API, as opposed to a formulation-induced food effect. The invention represented a "first of its kind," which is a strong indicator of inventiveness.

[23] In my view, Cipla's argument is a classic example of hindsight reasoning. With the benefit of knowing that the invention works, it is easy to piece together elements from the prior art and argue that the step was obvious. However, the proper question, viewed without the benefit of hindsight and through the eyes of a skilled formulator at the priority date, is whether there was a reasonable expectation of success that would warrant taking this specific path. The evidence establishes that there was none.

[24] I therefore find that Cipla has failed to discharge the onus of proving that the claimed invention was obvious. The attack on the ground of obviousness fails.

INSUFFICIENCY AND LACK OF CLARITY

[25] Having found that paragraph [0014] is not a definition that imposes a separate *in vivo* requirement, the grounds of insufficiency and lack of clarity, which were predicated on Cipla's interpretation, largely fall away. The claims, on their proper construction, define the monopoly by reference to the composition and its *in vitro* dissolution profile. These are matters that can be determined by a skilled formulator using standard, routine tests, without undue burden or prolonged research. The specification provides numerous examples (Examples 1-17) and teaches how to make formulations that meet the claimed

dissolution profile.

[26] Professor Davies' unchallenged evidence was that a skilled formulator would understand that if a formulation meets the dissolution profile of claim 1, it will reduce the food effect. Professor Walker could not gainsay this evidence by Professor Davies. No evidence was led by Cipla that there were trials on the food effect which was complex, took time and was difficult. The court is obliged to accept the expert evidence of Professors Dressman and Davies that conducting such clinical tests are routine and easy to conduct.

[27] The argument that the claim is insufficient because a clinical trial would be required to prove a reduction in food effect is based on a misreading of the claim. The claim does not require that a clinical trial be performed. It defines a product. The patent teaches that a product meeting the claim's limitations will have the property of reducing the food effect. For the purposes of sufficiency, it is enough that a skilled addressee can make the product. The fact that a clinical trial might be used to *verify* the product's therapeutic effect does not render the patent insufficient.

[28] Similarly, the claim is clear. The skilled formulator knows what a hydrogel-forming polymer is, what a hydrophilic base is, how to measure molecular

weight or viscosity, and how to conduct a USP paddle dissolution test to determine the claimed dissolution profile. The presence of illustrative examples in paragraph [0014] does not introduce ambiguity; it simply provides guidance. There is no "reasonable uncertainty" that would invalidate the claim for lack of clarity.

[29] Cipla's reliance on the fact that the Plaintiffs themselves relied on clinical data to prove infringement in this case is misplaced. Litigation is a different context. Proving infringement to a court on a balance of probabilities is not the same as defining the metes and bounds of a patent monopoly for the purpose of enabling a skilled addressee. The two standards are not the same.

[30] Accordingly, the attacks based on insufficiency and lack of clarity are also dismissed.

RELIEF

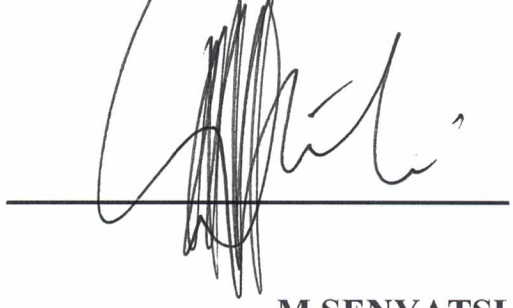
[31] The patent is valid. Cipla has conceded infringement. Astellas is therefore entitled to the relief it seeks. I will grant an interdict restraining further infringement, an order for delivery up of infringing products, and an enquiry into damages or a reasonable royalty, as is customary in patent matters. A certificate of contested validity in terms of section 74 of the Act is also

appropriate.

ORDER

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

1. The Defendant's counterclaim for the revocation of South African patent No. 2011/02406 is dismissed with costs, including the costs of two counsel and the qualifying fees of the Plaintiffs' expert witnesses.
2. The Defendant is interdicted and restrained from infringing South African patent No. 2011/02406 by importing, manufacturing, offering for disposal, or disposing of URTON, or any other product that falls within the scope of the claims of the said patent, in South Africa.
3. The Defendant is ordered to deliver up for destruction any URTON product in its possession or under its control.
4. There shall be an enquiry into the damages suffered by the Plaintiffs as a consequence of the Defendant's infringement of South African patent No. 2011/02406, and the Defendant is ordered to pay the amount of damages found to have been so suffered; alternatively, there shall be an enquiry into the amount of a reasonable royalty payable by the Defendant in lieu of damages, and the Defendant is ordered to pay the amount of royalties found to be so payable.
5. In the event that the parties are unable to agree on the procedure for the enquiry, they are granted leave to apply to this court for directions.
6. A certificate of contested validity is issued in respect of claims 1 to 10 of South African patent No. 2011/02406.



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JUDGE OF THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, PRETORIA

JUDGMENT DATE: 13 July 2026

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