

## WHY HAS HJI FILED AN OBJECTION TO THE GRANT OF A PATENT APPLICATION FOR A **KEY DIABETES MEDICINE?**



On 31 March 2025, the Health Justice Initiative (HJI) filed a formal objection with the Companies and Intellectual Property Commission (CIPC) against the grant of a patent application for a type 2 diabetes drug. The objection is aimed at preventing **“evergreening”**—a strategy used by pharmaceutical corporations to extend their monopolies on known medicines by filing successive patent applications on obvious improvements and forms. These attempts at extended monopolies keep prices high and delay the entry of affordable generic medicines into the South African market.

### WHAT IS EVERGREENING?

Evergreening is the practice whereby pharmaceutical firms extend monopoly protection, potentially indefinitely, by patenting modifications of an existing drug, delaying generic production of the drug beyond the original 20-year patent (MSF AC).



In this case, **Eli Lilly** is attempting to extend its monopoly on **Tirzepatide**, a diabetes and weight loss drug, by filing multiple patent applications in South Africa. If successful, this latest application would extend the patent and the monopoly until **2043**, despite existing patents already providing coverage until **2037** and **2039**. HJI's objection seeks to stop this unwarranted extension.

By opposing this patent *before* it is granted, HJI seeks to protect public health by alerting CIPC and the Registrar of the patent office to potentially unjustified attempts to prolong market control which also blocks generic competition.

## WHY IS THE DRUG TIRZEPATIDE IMPORTANT?



Tirzepatide is a dual GIP and GLP-1 receptor agonist (RA). These medications are becoming important for their effectiveness in managing type 2 diabetes, especially in patients at high-risk of cardiovascular disease. GLP-1 RAs not only improve glycaemic control but also provide cardiovascular and renal protection. Consequently, they have been incorporated into multiple treatment guidelines and standards of care, particularly in high-income countries.

Tirzepatide is a drug administered as a once-weekly subcutaneous injection, available in strengths ranging from 2.5 mg to 15 mg.

Like Semaglutide (Ozempic, Wegovy) Tirzepatide is approved by the U.S. Food and Drug Administration (FDA) for the treatment of type 2 diabetes and chronic weight management in adults with obesity.

In South Africa, Tirzepatide is registered by South African Health Products and Regulatory Agency (SAHPRA) and sold under the brand Mounjaro. Eli Lilly currently charges:

- ZAR 877 for a 2.5 mg or 5 mg vial
- ZAR 1141 for a 7.5 mg or 10 mg vial

Depending on the prescribed dose (which may increase up to 15 mg weekly), patients could pay ZAR 877 to ZAR 2,282 per week. Such pricing is unaffordable for many patients and reinforces the importance of generic competition to bring prices down.

## UNDER WHAT LEGAL PROVISIONS DID HJI FILE THIS OBJECTION?



Section 25 of the Patents Act 57 of 1978 (“the Act”) governs applications for patents. Section 25(1) of the Act states that a patent may only be granted if the invention is new, involves an inventive step and is capable of being used in industry. These are the requirements for patentability in South Africa.

HJI has filed an objection and has argued that Eli Lilly’s application does not meet the criteria under Section 25(1) in terms of **Regulations 54 and 55 of the Patent Regulations, 1978 (GNR 2470)**. These regulations establish an **opposition system** that allows any person to object to a patent application before the Registrar, within two months of the patent application being published in the Patent Journal.

Specifically, Regulation 54 provides that any party notified of a proposed action by the Registrar such as the patent applications listed in the Patent Journal—may lodge an objection within two months of publication. Therefore, we have argued that patients and/or public interest groups such as HJI should be able to object and oppose the grant of the patent by lodging their objections in form P15 between the date of publication and the grant of the application.

HJI has simply come forward to seek application of these provisions of the law. HJI’s objection to the grant of this patent is a lawful action under this framework, and while the first, it is a **notable use** of this underutilised mechanism to protect public health.

# WHY IS THE OPPOSITION IMPORTANT?

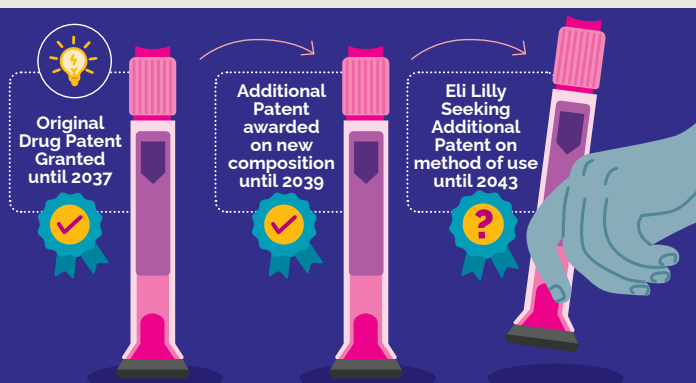


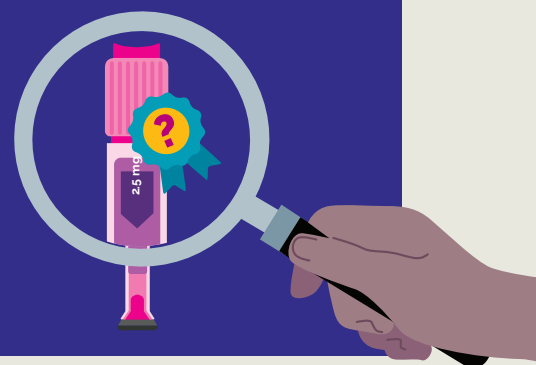
Image inspired by MSF Access Campaign

The opposition can help to:

- **Prevent evergreening of patent monopolies:** It helps avoid the grant of weak or undeserved patents, which can harm competition and delay access to medicines, thus protecting the constitutional right to access to healthcare.
- **Promote transparency and accountability:** It allows patients, public interest groups, and other stakeholders to ideally participate in patent examination processes.

Opposition systems (and substantive examination systems) are routinely used in countries such as **India, Brazil, Argentina, and China** to challenge evergreening patent claims before they are granted. In South Africa, this mechanism can be a vital tool to prevent the issuance of undeserved patents that could harm competition and availability of medicines for epidemics such as HIV and diabetes.

# HOW DID HJI IDENTIFY THE PRESENT **PATENT APPLICATION** FOR FILING AN OBJECTION?



HJI's researchers identified published patent applications on several important medicines, particularly those that would extend a patent monopoly term through evergreening. HJI researchers manually searched the 29 January 2025 *Patent Journal* published by CIPC.

- HJI scrolled through over 100 pages of the monthly CIPC *Patent Journal*, which included all published patent applications in that month.
- Unlike other Patent Office Journals that clearly label bibliographical data for pharmaceutical patent applications, these applications were published without labelling the fields of information related to claimed inventions.
- Additionally, the publication lacks important information such as the field of technology and international application numbers, making the search process lengthy and difficult.
- Despite these challenges, HJI identified Patent Application No. 2024/09805, filed by Eli Lilly which concerns the composition and use of Tirzepatide.
  - Form P25 obtained from CIPC database revealed that application 2024/09805 was the national phase entry of international application PCT/US2023/068925.
  - HJI obtained the patent claims from the PATENTSCOPE database, which provides access to published international PCT applications in full text, including bibliographic data, descriptions, claims, and related documents.

# WHAT ARE THE GROUNDS FOR HJI'S OPPOSITION?



HJI has argued that Eli Lilly's application 2024/09805 is a blatant and mala-fide attempt to evergreen its patent monopoly.

This is why:

- **Evergreening:**

Eli Lilly already holds three patents on Tirzepatide in South Africa:

- Compound patent (ZA201703930), expires **2037**
- Two other method-of-use/composition applications (2020/07162 and 2021/00062), extend the monopoly until **2039**
- 2020/07162 and 2021/00062—already covers the method of use or composition of Tirzepatide. Eli Lilly is pursuing a fourth monopoly with patent application 2024/09805 on the same composition to extend the monopoly until **2043**.

- **Does not meet the patentability criteria:**

- The 2024/09805 patent application does not disclose a new invention, and the preparation of pharmaceutical compositions requires the use of techniques commonly known to a person skilled in that field.
  - HJI further stated in its opposition that the claims in this application pertain to an alleged invention involving a method of treatment of the human body by therapy. According to Section 25(11) of the Patents Act, such inventions are deemed not to be capable of being used or applied in trade or industry and are therefore not patentable in the first instance. As such, the application fails a fundamental requirement of patentability under South African law.
- HJI argued that the application fails key patentability criteria and that granting it would unduly extend Eli Lilly's monopoly until 23 June 2043—restricting access to this important type 2 diabetes medicine. As such, HJI calls for the proper examination and rejection of this application thereby denying undue extension of a patent monopoly on a known medicine.

# WHAT IS THE **RESPONSE** OF CIPC TO THE OPPOSITION BY HJI, AS AT 16 JUNE 2025?



First response: 4 April 2025

“ Please note that the Registrar will consider the matter & afford both parties an opportunity to be heard. We shall revert after conducting a further investigation into the matter.”

Second response: 22 May 2025

“ ...please note that there is no procedure in our law to oppose the grant of a patent before the Registrar of Patents. The correct procedure would be to file a Form P20 for the revocation of a patent before the Commissioner of Patents or any other cause deemed suitable. Further, please note that only a patent attorney may act as representation before the Registrar of Patents”.

## **HJI disputes this interpretation.**

- HJI has fully complied with all procedural requirements under Regulation 54 and 55
- The relevant patent application was advertised in *E-Journal, Part 2*, on Wednesday, 29 January 2025.
- Regulation 54 expressly states that “**any person**” may oppose an action to be determined by the Registrar.
- HJI served its objection on the applicant's legal representatives on Monday, 31 March 2025, within the two month period.
- Proof of service and the opposition (lodged on Form P15 as required in Regulation 55) were filed with CIPC on the same day.

HJI is now demanding that its opposition to patent application 2024/09805 be properly considered on its merits and that the Registrar provide written reasons for the determination. Pending this consideration, HJI asserts that the patent should not be granted. HJI has also asked that detailed written guidance be given on the alleged requirement that only patent attorneys may appear before the Registrar.

## **CONCLUSION**

This opposition by HJI is important as the Bill to fix the Patents Act No. 57 of 1978 which seeks to introduce provisions to reform the current depository system - has been inexplicably delayed for several years by the dtic Minister. HJI's opposition is a strategic legal intervention to uphold South African law, prevent patent abuse, and promote equitable access to affordable medicines—particularly for chronic conditions such as diabetes. The case highlights the importance of public participation in the patent examination process and the urgent need to address evergreening practices by reforming South Africa's outdated depository patent system.