MSF and Health Justice Initiative welcome J&J's withdrawal of patents on lifesaving TB drug in South Africa

Today's patent withdrawal is a result of an unprecedented investigation by South Africa's Competition Commission into J&J

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Background:

Last year, on 23 March 2023, a <u>patent challenge</u> initiated in 2019 in India by two tuberculosis (TB) survivors, Nandita Venkatesan from India, and Phumeza Tisile, a TB treatment activist from South Africa, was successful and resulted in the Indian Patent Office <u>rejecting</u> the US pharmaceutical corporation Johnson & Johnson's (J&J) attempt to extend its monopoly in India on the TB drug bedaquiline, beyond the primary patent's expiry of July 2023. This was a significant step towards opening up generic competition for this lifesaving TB drug. However, at the time, South Africa would not have been able to benefit from generic competition as J&J's secondary patent would have enabled an extension of the corporation's monopoly on bedaquiline in South Africa until 2027 – a tactic known as <u>evergreening</u>. The result of such "evergreening" would have blocked less expensive, generic bedaquiline from entering the country.

Since June 2023, South Africa was buying bedaquiline directly from J&J at 5577 rand (US\$306) for a 6-month course per person, while countries procuring through the GDF (which South Africa cannot procure through) were paying less than half this price, at 2,446 rand (\$134) for a 6-month course (without potential local charges, e.g. VAT).

On 15 September 2023, the South African Competition Commission <u>launched</u> an <u>investigation</u> into J&J's evergreening patenting practices and anti-competitive pricing conduct. Almost immediately in September 2023, J&J <u>announced</u> that it would not enforce its secondary patents in 134 LMICs, including South Africa. Now, following the result of the Competition Commission's investigation initiation, J&J is not just lowering its price, but will withdraw the related secondary patents in South Africa, a move which Médecins Sans Frontières/Doctors Without Borders (MSF) and the Health Justice Initiative (HJI) welcomed as a significant step to increase access to affordable bedaquiline in South Africa, a benefit to the hundreds of thousands of people affected by TB in South Africa.

Candice Sehoma, Advocacy Advisor, MSF Access Campaign, South Africa:

"We welcome today's news that following the Competition Commission's investigation initiation into anticompetitive practice, J&J has officially withdrawn its secondary patents in South Africa on the lifesaving TB drug bedaquiline, opening up generic competition in South Africa.

"In particular, we welcome the Competition Commission's efforts in recognising J&J's tactic of patent evergreening as a blatant attempt by a pharmaceutical corporation to extend its monopoly and put its profits before people, and we applaud the Competition Commission prioritising the tackling of similar issues.

"We hope that this significant step will increase access to affordable bedaquiline for people living with TB in South Africa, as the country will now be able to purchase more affordable, generic versions of bedaquiline and could see more generic producers enter the market to bring the price of bedaquiline even lower, and ultimately, save more lives from TB."

Fatima Hassan, Founder of Health Justice Initiative, South Africa:

"Today's Competition Commission (CC) announcement is an important beginning and serves as a warning signal to the global pharma industry: there will be consequences to the abuse of the patent system!

"We are encouraged that the competition regulator is finally taking the matter of health product patent evergreening seriously – we will support it to do so in its future investigations. Today's capitulation by J&J, and the announcement of the CC, come off the back of years of TB activism and must mark the beginning of many more investigations into the rampant incremental patenting in South Africa from global corporations that are getting a free ride through South Africa's outdated and apartheid era patenting regime.

"South Africa's Companies and Intellectual Property Commission (CIPC) should not be doling out patents, they should be examining the merits, and we should be given the opportunity to oppose such applications – as is our Constitutional right – otherwise more people will get sick and die needlessly in South Africa while corporations make incredulous profits. Going forward, pharmaceutical corporations need to be held in check and to account, and this is why as HJI we call on the new South African Trade, Industry and Competition Minister (dtic) Minister, Parks Tau, to expedite South Africa's patent law amendments, as his predecessor failed to do so even during a pandemic.

"Our only regret today is that J&J was not compelled to pay a hefty fine for taking advantage of the weak patent laws in our country to drive up profits, charge exploitative prices, and exercise monopoly control. Hopefully, the CC's investigation will also be a warning sign to other corporations that are benefiting from an indefensibly lax patenting regime in South Africa and elsewhere in Africa – these corporations must now be interrogated and investigated by regulatory agencies for pricing and evergreening patenting strategies for several key medicines needed to prevent and treat HIV, cancer, cystic fibrosis, TB and other diseases affecting our people."

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