

## Changes to intellectual property policy in South Africa: putting a stop to evergreening?

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## EXPERT OPINION

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# Changes to intellectual property policy in South Africa: putting a stop to evergreening?

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South Africa is a middle-income country with the world's largest HIV patient cohort and a growing burden of communicable and non-communicable diseases – a prime location for pharmaceutical companies looking to expand their markets. Yet, 20 years after the country's first democratic elections, poor health indicators and an over-burdened public health system belie persistently stark levels of socioeconomic inequality. As the South African government revises national intellectual property (IP) policies, the pharmaceutical industry and global access to medicines movement are watching, aware of ramifications South Africa's actions will have on patent laws and the availability of generic medicines in other middle-income countries and across Africa. South Africa's draft IP policy is meeting fierce resistance from industry, although proposed reforms are compliant with the Agreement on trade related aspects of intellectual property (TRIPS) and in line with on-going policies and actions of both developing and developed countries. Could the establishment of a patent examination system and new patentability criteria rein in evergreening and lead to lower medicine prices? What will be the potential impact of reform on medical innovation? And why is it both necessary and urgent that the South African government seek a fairer balance between private and public interests?

**Keywords:** evergreening, innovation, intellectual property reform, patent examination, patentability criteria, pharmaceutical patents, Pharmagate, South Africa, TRIPS flexibilities

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## 1. Introduction: what is at stake in South Africa's intellectual property debate?

In January 2014, South Africa's *Mail & Guardian* ran a front-page headline quote from the Minister of Health, Aaron Motsoaledi: 'This is genocide' [1]. The accused was the Innovative Pharmaceutical Association of South Africa (IPASA), a trade association of 26 multinational pharmaceutical companies. A leaked strategy document drafted by US lobbying firm Public Affairs Engagement (PAE), accompanied by an email from Merck Sharp & Dohme's Michael Azrak to other companies' IPASA Board representatives, outlined a plan to covertly delay the South African government's finalization of a new national intellectual property (IP) policy [2]. With financial backing from the Pharmaceutical Research and Manufacturers of America (PhRMA), IPASA budgeted US\$600,000 to utilize South African organizations and politicians as a front for promoting their policy objectives. Motsoaledi's reference to a 'satanic plot' may suggest hyperbole, but his concerns should not be dismissed lightly.

A battle is underway in South Africa – terrain the PAE strategy referred to as 'ground zero' for companies aiming to protect pharmaceutical IP rights in MICs and growing African markets. South Africa is a country where over two million

patients have initiated antiretroviral therapy, over 14,000 drug-resistant tuberculosis (DR-TB) infections were recorded in 2012, and there is a growing burden of non-communicable diseases [3-5]. Yet, half the population lives on < \$3/day, and public health spending – a staggering 11% of the annual government budget – supports over 80% of the population's health needs, although expenditures per capita in the private system are up to ten times higher [6].

The point of contention is the *Draft National Policy on Intellectual Property, 2013* (DNPIP), released by the Department of Trade and Industry (DTI) for public comment in September 2013 [7]. The DNPIP's most significant reforms are those addressing the effects of patent laws on public health, and seeking to keep medicine prices in check by facilitating the timely use of flexibilities outlined in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Many reforms are vocally supported by the 'Fix the Patent Laws' campaign – a civil society coalition led by the Treatment Action Campaign, Section27 and Doctors Without Borders (MSF) [8]. The multinational pharmaceutical industry, by contrast, is attempting to preserve the existing climate in South Africa, which is one of the most lenient in the world in granting patents and has limited effectiveness employing TRIPS flexibilities to access more affordable generic medicines.

Recent public backlash against 'Pharmagate' evokes déjà vu from 1998. Then, 39 multinational pharmaceutical companies took Nelson Mandela's government to court, questioning South Africa's right to import cheaper medicines from other jurisdictions. The laws in question were fully TRIPS-compliant – in fact, a product of technical assistance from the World Intellectual Property Organization [9]. In light of this, and facing a public relations disaster, the pharmaceutical companies were eventually forced to drop the case and accept that they could not bully the country into creating pro-industry laws that ignored public health considerations. The case eventually galvanized a World Trade Organization agreement: the Doha Declaration on TRIPS and Public Health, which stated unequivocally that 'the TRIPS Agreement does not and should not prevent members from taking measures to protect public health'.

Reforms proposed in the DNPIP are a continuation of previous government efforts to meet the state's obligations under Section 27 of the South African Constitution. 'The state must take reasonable legislative and other measures' to progressively realize the right of everyone in South Africa to have access to healthcare services, which includes access to medicines [10]. With IP policies that are outdated, unimplemented or incoherent due to *ad hoc* legislative changes since the end of apartheid, several substantial tasks lie ahead. Most notably, the DTI intends to establish a substantive patent examination system and supplementary measures to curb the practice of evergreening, and positively influence competition, affordability and innovation in the pharmaceutical market [11].

This article focuses on why patent evergreening is problematic in blocking access to affordable medicines in South Africa, and which proposed reforms, once implemented,

could stop frivolous granting of pharmaceutical patents and enhance cost savings. The article also considers the impact stopping evergreening will (or will not) have on innovation for developing medicines needed in South Africa, and how South Africa's government could continue to defy industry pressures by prioritizing the finalization and implementation of a national IP policy.

## 2. Pharmaceutical patent evergreening: limiting competition in South Africa

South Africa's patent office, which is housed within the Companies and Intellectual Property Commission (CIPC), does not substantively examine patent applications to ensure national criteria for granting a patent are met. Instead, CIPC registers any patent when the proper paperwork is filed and fees paid [12]. Pharmaceutical companies take advantage of this lack of scrutiny by filing new patent applications on minor modifications of existing products (e.g., on a combination of several drugs in one pill, a new use for a drug, a reformulation), typically several years after the initial patent was filed. This practice, known as 'evergreening', allows originator companies to continue blocking generic competitors from entering the market when the initial patent expires and maintain the ability to charge high prices. Although the practice of evergreening is not exclusive to South Africa, the problem there is particularly acute, due to the absence of an examination system. Because no complete application is rejected, South Africa grants an extraordinary number of patents on pharmaceuticals – 2442 patents in 2008 alone. By contrast, Brazil – which does conduct substantive examination – granted only 273 patents on pharmaceuticals between 2003 and 2008 [13]. South African patent practices are not only unusual for an MIC – in a sampling of identical pharmaceutical patent applications filed in various jurisdictions between 2000 and 2002; the US Patent and Trademark Office and European Patent Office both rejected ~ 40% of the applications granted by South Africa [14].

Proliferation of secondary patents creates a culture of uncertainty and leads to fear of patent infringement, thereby discouraging generic drug manufacturers from marketing more affordable medicines. For example, the original South African patent held by Novartis on cancer treatment imatinib expired in April 2013; however, a new-use patent on imatinib runs until 2022 [15,16]. Only one generic drug company, Cipla, has entered the market to date, after reaching an unpublicized agreement with Novartis. Other would-be competitors will also contend with Novartis until the secondary patent expires. To realize prices found in India – where, according to MSF, over ten competitors sell imatinib, and Cipla markets the drug at a price 91% lower than in South Africa – reform that promotes greater competition with multiple generic drug manufacturers on the market is necessary [17]. As a solution, in the DNPIP, the DTI proposes a multi-pronged approach to enhance both the standard for innovation to which a patent

application is upheld, and the scrutiny to which the application is subjected to ensure it meets national criteria.

### 3. Can IP reforms improve access to more affordable medicines?

The DNPIP recommends excluding from patentability ‘diagnostic, therapeutic and surgical methods..., including new uses of known products’, noting this is compliant with TRIPS. South Africa could also consider other countries’ recent interpretations of the definitions of ‘novelty’ and ‘inventive step’. For example, the Indian Patents Act’s Section 3(d) specifically acts to limit patent evergreening by excluding from patentability modifications of known substances (such as pharmaceuticals), unless the modification results in ‘enhanced efficacy’ [18]. New patent examination guidelines issued in Argentina contain more comprehensive exclusion criteria than India and no inclusion of an ‘enhanced efficacy’ provision [19]. Under this interpretation, if a pharmaceutical compound is part of the state of the art, the public health considerations of accessing more affordable generics outweigh commercial interests of the originator company. In the 5 months prior to the guidelines going into force, Argentina granted 53 pharmaceutical patents; in the 7 months following, it granted only two [20]. By enacting similar criteria, South Africa could easily reduce the number of pharmaceutical patents granted to a fraction of the current level.

New patentability criteria will have limited impact on evergreening, however, if the current patent registration system remains intact. The DNPIP identifies several ways to improve adherence to patentability criteria and the subsequent quality of South African patents granted. First, the DNPIP proposes the establishment of a patent examination system. This would bring South Africa in compliance with Section 34 of the Patents Act of 1978, which mandates substantive examination. To date, resources have not been allocated to implement such a system. Pre- and post-grant patent opposition would also be established to serve as an essential procedural safeguarding for the formal examination system. Unmentioned by the DNPIP are complementary reforms required to make proposed systems a reality: a plan must be established to recruit and train examiners; a viable fee structure for patent applications and maintenance will be necessary to sustain the increased human resources required by an examination system; and transparency of the CIPC should be enhanced through improved IT systems and online search capabilities, to facilitate examination and opposition procedures.

### 4. Ending evergreening in South Africa: only one step towards promoting needed medical innovation

Proposed South African reforms are discussed by the Pharmagate PAE strategy with a Cold War-era ‘domino effect’

mentality – another nation from the Brazil-Russia-India-China-South Africa (BRICS) group is falling into the morass of public health-oriented IP policy, with more countries to follow suit. Sub-Saharan Africa, however, makes up only 1.2% of global pharmaceutical revenues [21]. Curbing evergreening in South Africa – even as the largest emerging pharmaceutical market in the region – is unlikely to put a serious dent in the US\$600 billion in global annual revenues of the branded medicines market, or further reduce the already-low 16.4% of revenues PhRMA members claimed they spent on medical research and development (R&D) in 2012. More countries could weary of providing financial rewards for follow-on pharmaceutical modifications with limited to no therapeutic impact. If so, widespread rejection of frivolous patents and higher expectations for innovation could result in a refreshing new reality: rather than pharmaceutical manufacturers investing significant time and energy into development of me-too drugs, or tweaking existing compounds to extend the lifetime of a drug’s profitability, more resources might instead be devoted toward R&D for a greater number of new drugs and breakthrough forms of treatment.

Limiting evergreening would facilitate the development of competitive markets when demand for medicines spans both wealthy and poorer economic classes. A patent examination system, however, is unlikely to either hinder or help R&D investment for treatments needed almost exclusively by poorer South Africans. Current innovation models are dependent on products’ commercial viability to create a return on investment in R&D, and have historically neglected the medical needs of low-income populations. Different incentives are needed – referred to as ‘alternatives to IP’ in the DNPIP – to develop treatments the pharmaceutical industry has abandoned or ignored, and ‘de-link’ the cost of R&D from the private sector’s *modus operandi* of charging high prices to re-coup investment. Early-stage financing for neglected areas of research, push funding that can finance pre-clinical R&D or clinical trials, milestone and end-stage prizes that are conditional on the open licensing of IP, and market shaping that encourages competition, could all contribute to de-linking [22]. New IP policies in South Africa should ensure medical innovation financed with public funds is coupled with government actions that promote the principles of de-linkage and affordability, so that needed therapies do not fall by the wayside due to lack of commercial interest.

### 5. Expert opinion

The government of South Africa has both national obligations and rights under international agreements to develop policies to protect access to lifesaving medicines, and to promote the development and affordability of needed new treatments. National political will is often the only way to counter the ostentatious Pharmagate assumption that industry cash flows can block a country’s adoption and implementation of TRIPS flexibilities. The public health protections enshrined in the

Doha Declaration must take precedent over opinions founded in corporate interest, such as Bayer CEO, Marijn Dekkers' recent statements that his company's cancer treatment was not developed for the Indian market, but 'for Western patients who could afford [it]' [23].

For the DTI to better ensure affordability of medicines to rich and poor alike in South Africa, it must put a stop to evergreening. Expanded justifications for establishing a patent examination system, new patentability criteria, patent opposition and other reforms should be incorporated into a finalized IP policy. The DTI promises policy finalization is underway, led by an inter-departmental government task force [24]. This task force should proactively detail how it envisions the establishment of systems already mandated by law – particularly, a patent examination system.

Building capacity of patent examiners will require a sustained, multi-year effort and adequate financial resources, but South Africa does not need to create the system from scratch, nor wait years to start examining pharmaceutical patents. It can draw upon the recent experiences of, and reach out for technical assistance from BRICS partners Brazil and India, which have implemented reforms to limit evergreening in the recent past. To address potential capacity constraints, South Africa could prioritize training of patent examiners in fields relevant to the public interest, such as pharmaceuticals. In order to maintain compliance with Article 27.1 of TRIPS, South Africa could also detail a schedule for the eventual examination of all patent categories.

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Patent thickets have already sprung up in South Africa around promising new treatments for drug-resistant forms of HIV and TB. These patents interfere with access and with development of appropriate regimens and fixed dose combinations. If South Africa is to have the legal tools available to challenge patents granted too easily and to reject patent applications that are meritless, IP reform cannot be delayed.

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## Declaration of interest

JE Hill is the Access Advocacy Officer for Médecins Sans Frontières/Doctors Without Borders (MSF) in Johannesburg, South Africa. MSF is a partner in the South African civil society coalition comprising the 'Fix the Patent Laws' campaign. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. The views expressed are the author's own, and not necessarily an official position of Doctors Without Borders or the 'Fix the Patent Laws' campaign.



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