Strategic Patenting and its Impact on Competition: Evidence from the South African Pharmaceutical Sector

WORKING PAPER CC2024/01

Thembalethu Buthelezi and Tankiso Thibane

Abstract

This paper has considered the trends in patent applications for pharmaceutical drugs used to treat Diabetes, Tuberculosis (TB) and human immunodeficiency virus (HIV), which are three chronic diseases with high prevalence and cause death in South Africa. The first part of the analysis considered the market structure landscape in terms of patent filings by assessing active and expired patents on molecules that treat the three diseases. The second part of the analysis examined whether there is existence of any form of strategic patent behaviour at molecule level that may potentially have implications on competition.

Having broadly analysed the trends and behaviour in patent applications, the implications of this research are two-fold. One, from a policy perspective, the implementation of the TRIPS flexibilities would enable the implementation of a more substantive and rigorous patent system. Under the current South African patent system, the novelty or inventive merit of the invention is not substantively examined. The system fundamentally misses out on protecting patents for a set period only after the examination of the patentability of the invention. To this end, a substantive search and examination patent system will be part of the solution. Two, competition law and enforcement, has a role to play in addressing competition issues arising from strategic patenting conduct by pharmaceutical firms. Specifically, potential abuse of market power can be addressed by the Competition Act, through enforcement interventions against exploitative and exclusionary conduct by firms.

Keywords: Strategic patenting, HIV, TB & Diabetes

1. INTRODUCTION AND BACKGROUND

Pharmaceuticals are regarded as an important input into the delivery of healthcare services from a public interest viewpoint. For this reason, the pharmaceutical industry is heavily regulated, including all aspects of the life cycle of new drugs, pricing, and patent application to marketing approval and patent expiration. Despite these regulations, high prices remain an overarching feature of the pharmaceutical sector. The problem of high drug prices has been inflating healthcare budgets and posing a serious risk to the affordability and accessibility of medicines for society[1] [2] [3].

In addition, current statistics indicate that the number of new breakthrough medicines is decreasing, and this is despite the alleged surge in investments in pharmaceutical research and development[4][5]. On the other hand, the number of drugs that contain modifications of existing medicines is growing, suggesting that pharmaceutical companies have been increasingly focusing their research on incremental drug development, rather than on breakthrough innovation[6][7][8][9]. In their defence, pharmaceutical companies have cited the complexity of drug discovery and development, as well as the expensive and lengthy regulatory procedures involved as factors that give rise to the high drug prices and the growing incremental invention[10] [11] [12] [13].

While these reasons are noted, some practices by pharmaceutical companies substantially contribute to high drug prices and incremental innovation. Pharmaceutical companies have been increasingly engaging in strategic patenting to delay or even block generic competition[14]. South Africa is not

---

[1] Kesselheim, A. S., Avorn, J., & Sarpatwari, A. (2016). The high cost of prescription drugs in the United States: origins and prospects for reform. *Jama*, *316*(8), 858-871.

[2] Secretariat, U. N. C. T. A. D. (2015). The role of competition in the pharmaceutical sector and its benefits for consumers: note/by the UNCTAD secretariat.

[3] Hubbard, T., & Love, J. (2004). A new trade framework for global healthcare R&D. *PLoS biology*, *2*(2), e52.

[4] Pammolli, F., Magazzini, L., & Riccaboni, M. (2011). The productivity crisis in pharmaceutical R&D. *Nature reviews Drug discovery*, *10*(6), 428-438.

[5] Scannell, J. W., Blanckley, A., Boldon, H., & Warrington, B. (2012). Diagnosing the decline in pharmaceutical R&D efficiency. *Nature reviews Drug discovery*, *11*(3), 191-200.

[6] I-Mak, O. overpriced: how excessive pharmaceutical patenting is extending monopolies and driving up drug prices, 2018. *Disponible sur: https://www. i-mak. org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices*

[7] Correa, C. M. (2011). *Pharmaceutical innovation, incremental patenting and compulsory licensing* (No. 41). Research Paper.

[8] Ho, C. M. (2014). Should All Drugs Be Patentable: A Comparative Perspective. *Vand. J. Ent. & Tech. L.*, *17*, 295.

[9] LIGHT, D., & Lexchin, J. (2012). PHARMACEUTICAL R&D What do we get for all that money?. *BMJ (Overseas and retired doctors ed.)*, *345*(7869), 22-25.

[10] EFPIA (2018) The pharmaceutical industry in figures. Key Data 2018 https://efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf (Accessed: 6 July 2022

[11] Keyhani, S., Diener-West, M., & Powe, N. (2005). Do drug prices reflect development time and government investment?. *Medical Care*, 753-762.

[12] Matthews (2015): Forbes: The High Cost Of Inventing New Drugs – And Of Not Inventing Them. Available at: https://www.forbes.com/sites/merrillmatthews/2015/04/11/the-high-cost-of-inventing-new-drugs-and-of-not-inventing-them/?sh=27ca26bf1c49 (Accessed: 06 July 2022)

[13] DiMasi, J. A., Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: new estimates of drug development costs. *Journal of health economics*, *22*(2), 151-185.

[14] European Commission, 2009: Pharmaceutical Market Inquiry. Available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (Accessed: 04 July 2022)

immune to strategic patenting, and this is even more so given its patent system which does not appear to adequately prevent such practices. South Africa does not examine the patentability of the patent in terms of the patentability requirements provided for in the Patents Act No 57 of 1978 but rather examines compliance with formalities. The patent office works on the assumption that once an application has been filed, what is claimed to be an invention deserves a patent. This means that a patent is granted on all applications that sufficiently comply with the formalities.

Considering the above, this research provides an overview of trends in the patent applications and strategies observed in pharmaceutical products used to treat three prevalent diseases, human immunodeficiency virus (HIV), tuberculosis (TB) and Diabetes. To do this, this research has relied on publicly available patent information on the pharmaceutical products treating the three prevalent diseases. The research considers the trends observed in patent applications from the main manufacturers of drugs used for the treatment of HIV, TB, and diabetes. Estimated market shares are presented to provide a snapshot of the market structure from a patent perspective. To provide preliminary insight into potential strategic patenting, the research highlights instances where (i) multiple patent applications have been filed by manufacturers and (ii) patents filed by manufacturers and there is no supply in the market. Given the limitation of using publicly available information, this research may only highlight insights on patent trends as observed from the data but is unable to provide positive confirmations of strategic patenting conduct by manufacturers.

The remainder of this research is structured as follows: **Section 2** provides a discussion on patent legislation and access to medicine. **Section 3** discusses competition issues arising from the strategic use of patents in the pharmaceutical sector. **Section 4** illustrates patent trends and behaviour related to pharmaceuticals and the prevalence of potential strategic patenting in South Africa. Lastly, **section 5** provides research observations and conclusion.

2. SOUTH AFRICA'S PATENT LEGISLATIVE FRAMEWORK

The pharmaceutical sector in South Africa is governed by policies that set out the framework for achieving affordable and accessible medicines for all South Africans. One of the preliminary policies was the National Medicine Policy of 1996 which sets out specific health, economic and national development objectives to inform medicine policy and regulation. Recent developments include the National Health Insurance White Paper (2017) and the National Health Insurance Bill (2019) which aim to improve the overall functioning of the healthcare system, including increasing the affordability and accessibility of medicines in SA.

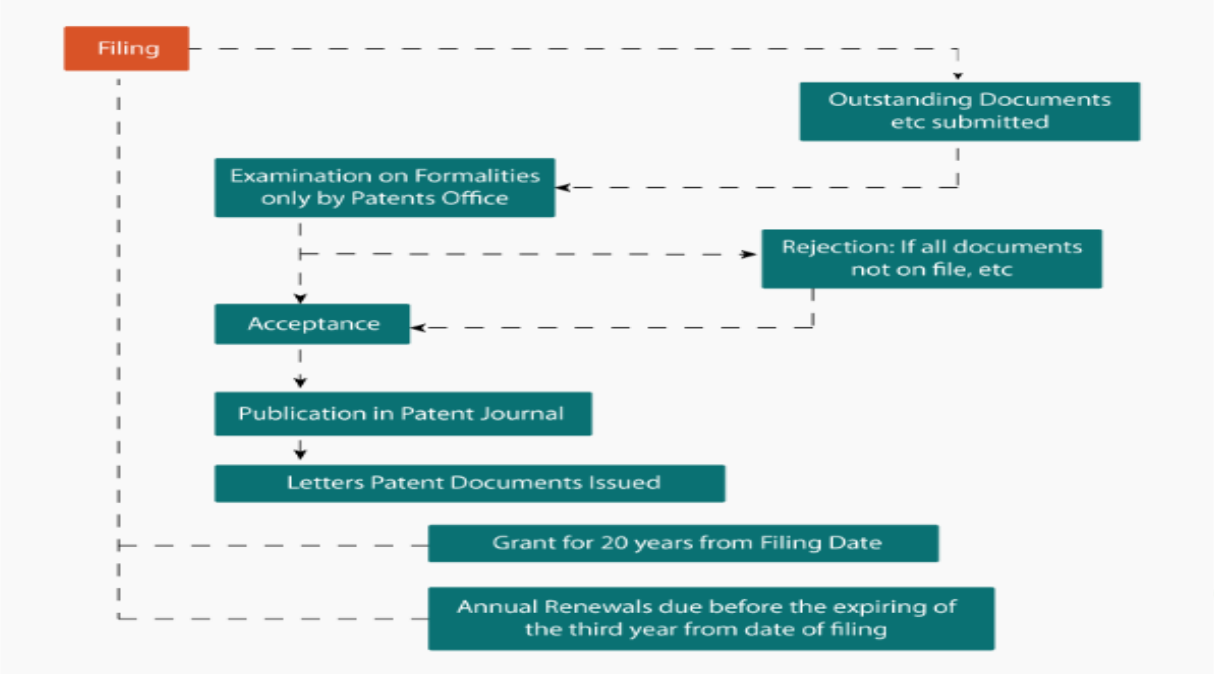
In South Africa, the patent regulations are encapsulated in the Patents Act (no. 57 of 1978) – which is administered by the Companies and Intellectual Property Commission (CIPC), at least to the extent

that it relates to the registration of patents, maintenance of data, publication of a patent journal and the administration of the Court of Commissioner of Patents. Although CIPC's primary institutional mandate is derived from the Companies Act 2008, which establishes CIPC as a juristic person, it also performs the role of a patent office – as established in terms of section 5 of the Patents Act (1978). The Patents Act (1978) also provides for the establishment of the Registrar of Patents[15] and the Commissioner of Patents[16].

The patent filing or application process comprises of five steps namely (i) register as a customer – to enable for the creation of a unique customer code; (ii) deposit funds – these range between R60 and R590, depending on the nature of application; (iii) conduct a search – this is conducted to ensure that no existing patents are being infringed and that the invention is new or novel[17]; (iv) application of the patent – there are three types of patent applications and these include: (a) a provisional patent application[18] – this may be undertaken by the applicant with or without the assistance of an attorney; (b) a complete patent application – this must be signed by an attorney; and (c) a patent cooperation treaty (PCT) – this is done when the patent application is for different countries and the application comprises of two phases (i.e., PCT international and national phase); and (v) registration of a patent – once a complete patent application or PCT national entry has been lodged, the rest of the process takes the form shown in **Figure 1** below.

[15] The registrar of patents is appointed in terms of section 7 of the Patents Act
[16] The Commissioner of patents is appointed in terms of section of section 8 of the Patents Act.
[17] The requirement for novelty means that the invention must be new at the priority date of the invention anywhere in the world – not known through written or oral public disclosure or through use (CIPC, 2022). See, [17] CIPC, 2022. Patents. Available at: http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/patents/how-app/ (Accessed: 01 July 2022).
[18] This application fairly describes the invention and does not provide claims. Further, provisional applications have to be accompanied by a complete application within a period of 12 months.

Figure 1: Patent registration process in South Africa as of 2022



Source: CIPC[19]

Figure 1 shows that in South Africa, a patent application is accepted once all the formalities have been complied with. The examination is not necessarily on the patentability of the patent but rather on the compliance with formalities. To this end, the patent system applied in South Africa is not different to a 'depository system'. Under such a system, patents are granted on all applications[20] for which forms are correctly filed and fees are paid without a substantive examination of the application's merits.[21]

Notably, South Africa commonly grants many patents that are rejected or withdrawn in other jurisdictions where substantive examination of patent applications is conducted.[22] To illustrate South Africa's lack of substantive patentability criteria, a review of the outcome of matching pharmaceutical patent applications filed in different jurisdictions found South Africa to be an outlier in relation to the patent grant rate[23]. In this regard, Sampat and Shadlen (2016)[24] reported that on matching patent applications filed between 2000 and 2002, South Africa granted 93% of

[19] CIPC, 2022. Patents. Available at: http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/patents/how-app/ (Accessed: 01 July 2022)
[20] CIPC works on the assumption that once an application has been filed, what is claimed to be an invention deserves a patent.
[21] Tomlinson, C., Ashmore, J., Yawa, A., & Hill, J. (2015). Reforming South Africa's procedures for granting patents to improve medicine access. *SAMJ: South African Medical Journal*, *105*(9), 741-743.
[22] Tomlinson, C., Waterhouse, C., Hu, Y. Q., Meyer, S., & Moyo, H. (2019). How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies. *South African Medical Journal*, *109*(6), 387-391.
[23] Ibid.
[24] Sampat, B. N., & Shadlen, K. (2016). The effects of restrictions on secondary pharmaceutical patents: Brazil and India in comparative perspective. In *Proceedings of the 'Moral Economies, Economic Moralities' Conference, University of California* (pp. 1-49).

patents applied for, compared to 61% in the USA, 51% in Europe and 29% in Japan. Sampat and Shadlen (2016)[25] also noted that 'since South Africa does not examine applications, the only applications not granted appear to be those withdrawn during the examination process due to failure to pay issue fees, and (a very small number) applications still pending'.

The shortcomings of the South African patent system, to the extent that they relate to the non-examination of patentability, have broader implications on generic competition and access to medicine. Currently, the South African patent system may create a conducive environment for pharmaceutical firms, particularly originator drugs, to engage in strategic patenting. This is due to the fact that pharmaceutical companies can unduly lengthen their patents beyond the prescribed period of 20 years, with ease. This not only results in the prevention or lessening of competition (due to blocked or delayed market entry for generic medicines) but also reduces consumer access to innovative and affordable medicines. For example, generic competition is a critical market force that has driven down the price of HIV/ AIDS treatments from more than US$ 10 000 to less than US$ 99 per patient per year.[26]

Pharmaceutical companies do not usually apply for a single patent on a medicine, but rather file several patent applications for the same drug.[27] A number of different features may be the subject of patent applications, including the process used to manufacture the molecule, the formulation or form a medicine takes (i.e., powder, tablet, capsule, injectable, syrup, dispersible tablet, etc.), the dosage (including the route and the regimen), the act of putting a medicine in combination with another in the same pill, new uses of an existing medicine, derivative forms of a medicine (i.e., salts, pro-drugs, crystals, polymorphs), and even the raw materials used, such as active pharmaceutical ingredients and intermediates. As a result, a single medicine can have applications for several separate patents, each relating to a different aspect of the same medicine.

By filing multiple applications, pharmaceutical companies can extend their monopoly and defer the date on which their products go off-patent. This practice, known as "evergreening," prevents and delays the entry of important medicines into the public domain at a point when cheaper generic versions could be produced locally or imported. As such, countries such as South Africa, are more likely to grant multiple patents on a single medicine allowing for the evergreening to occur. By granting patents too easily on derivatives or on marginal improvements of existing drugs, the patent system is, therefore, unable to protect the public and generic competitors from

[25] Ibid.
[26] World Health Organization. (2014). *Access to affordable medicines for HIV/AIDS and hepatitis* (No. SEA-TRH-16). WHO Regional Office for South-East Asia.
[27] Spector, Risanne, 'Me-too drugs. Sometimes they're just the same old, same old, Stanford Medicine Magazine, Summer 2005, available at http://stanmed.stanford.edu/2005summer/drugs-metoo.html

unwarranted monopolies.[28] This is particularly worrying for South Africa given the heavy health burden faced by the public sector. The proliferation of 'undeserving' patents can impede the government's efforts to meet its constitutional obligation to provide access to health care.

3. SOUTH AFRICA'S PHARMACEUTICAL MARKET AND PATENT TRENDS

South Africa's pharmaceutical market is dominated by prescription medicine spending, including patented and generic medicine expenditure, which accounts for approximately 88.3% of the total market and over-the-counter (OTC) medicine spending representing the remainder of 11.7%.[29] Total pharmaceutical sales in South Africa were estimated at US $3.428 billion in 2018. Generic medicine sales were estimated at US $1.251 billion in 2018.[30]

There is strong support from government to increase the use of generics with the Medicines and Related Substances Act 101 of 1965 (as amended) (Medicines Act) containing provisions requiring pharmacists to inform private patients about generic alternatives when they purchase prescription medicines. The private healthcare sector also recognises the importance of using generics. Discovery Health (medical scheme administrator) finds that the use of cheaper, good-quality generic medicines can reduce healthcare inflation, saving as much as R1.5 billion per annum for medical scheme members, while a major hospital group had begun promoting the use of these medicines through its hospital pharmacies.[31]

By 2019, South Africa had granted approximately a cumulative total number of 667 patents on drugs. Of these, 46% patents were granted for HIV drugs – which is one of the major diseases causing death in South Africa[32]. During the period between 1986 to 2007, fluctuations in the number of patents granted on drugs were largely driven by changes in patents granted for HIV drugs. For instance, during the period between 1988 to 1990, there were about 78 patents granted on HIV drugs out of 82 patents granted on all drugs.

The ACF pharmaceutical study (2022) found that the South African pharmaceutical sector is highly concentrated with three local companies (Aspen, Adcock Ingram and Ascendi) and several

---

[28] https://www.fixthepatentlaws.org/resources/why-south-africa-needs-an-examination-system-tac-msf-ris-paper-2012/ [accessed 22 August 2023]

[29] Africa Health, Industry insights: South Africa healthcare market overview. https://www.africahealthexhibition.com/content/dam/Informa/africahealthexhibition/en/2020/pdf/AFH19_Industry_Insights-SA_MARKET_REPORT.pdf

[30] Roy Horner. Global value chains, imports orientation, and the state: South Africa's pharmaceutical industry. Journal of International Business Policy (2022) 5, 68–87.

[31] Chris Bateman, Promote cheaper generic medicines to patients – and help contain medical inflation, September 2014, SAMJ. S.Afr.med Vol. 104, No. 9.

[32] Statistics South Africa, 2021: Mortality and causes of death in South Africa: Findings from death notification. Available at: https://www.statssa.gov.za/publications/P03093/P030932017.pdf Accessed: 7 July 2022)

international players[33]. Notably, in South Africa, there are more wholly generic manufacturers than originator medicines. While South Africa does have some generic manufacturing production the generic market is still undeveloped and small with 58 companies supplying just over 5000 generic medicines for the local and export markets. Also, most of the API's are imported into South Africa. This market structure is of interest as it may also be a reflection of the patent system underlying the pharmaceutical sector.

Studies have shown that the patent registration system adopted by South Africa may have also contributed to the limited industrial capacity of the local manufacturing of pharmaceutical products. A study by the University of Pretoria estimated that around 80% of the patents granted in the country do not meet the country's patent standards.[34] A 2012 research report further revealed that South Africa grants 66% more patents than the United States and European Union on identical applications.[35] The ease in which pharmaceutical patents are granted in South Africa has meant that the country's local generic manufacturing sector has never had the opportunity to take off and compete with its international counterparts. Patenting by pharmaceutical companies has, thus, increasingly been found to present barriers to medicine access, particularly more so in the case of essential medicines.[36]

On the global front, there have been debates regarding the anti-competitive nature of strategic patenting. Key questions in this debate concern whether strategic patenting strategies may be deemed unlawful and violate competition law, while also being justifiable business practices under patent law. The loss of patent-protected exclusivity is known to be followed by severe losses in sales and profit to incumbent companies. This is largely because when the patent protection expires, generic manufacturers enter the market with drugs that are equivalent to the innovator's drug, but typically at a significantly lower price. For instance, the pharmaceutical market inquiry carried out by the EC in 2009 has shown that the average generic price, two years after its entry, is around 40% below the price of the former brand name products (European Commission, 2009).[37] This, of course, has enormous public interest benefits which include, among others, the following:

---

[33] See: https://www.compcom.co.za/wp-content/uploads/2023/08/pharmaceutical-report-final-5.pdf .
[34] Pouris A, Pouris A. "Patents and economic Development in South Africa: Managing intellectual property rights." S Afr J Sci. 2011;107(11/12), Art. #355, 10 pages. http://dx.doi.org/10.4102/sajs.v107i11/12.355
[35] See: https://www.fixthepatentlaws.org/wp-content/uploads/2016/09/MSF-FTPL-report-FINAL-VERSION.pdf
[36] Wen, Y. and Matsaneng, T. (2014) "Patents, Pharmaceuticals and Competition: Benefiting from an effective patent system". https://www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf
[37] Ibid.

(i) easing of pressure on public health budget; (ii) increase in consumer welfare – due to increased access; and (iii) creates incentives for future research – promotes innovation[38].

On the other hand, this means originator firms are confronted with drastically falling revenues, potentially prompting them to resort to anti-competitive measures to protect their market positions. To this end, pharmaceutical companies have been increasingly relying on the strategic use of the patent system to combat the pressure from generic competition[39][40]. Strategic patenting often amounts to anti-competitive behaviour, and thus may qualify as a prohibited act, in terms of section 8 of the Competition Act (1998), as it results in the exclusion of generic drug manufacturers and further enables the originator firms to charge excessive prices for their respective drugs.The underlying rationale for any pharmaceutical company to engage in strategic patent applications is best understood through the drug development process. This process consists of three stages:

a. The research and development stage – which ends with the launch of the drug on the market;

b. The period between the launch and patent expiry – it is during this stage when originators may seek to maximize their income from the drug in order to recoup the research and development investments made. This period also allows for the originator to earn profits before the commencement of generic competition; and

c. The period after patent expiration – this is when generic competition enters the market.

Firms will seek to prolong their market exclusivity, this is also known as 'life-cycle management', through the strategic use of patents to further protect the firm from competitive pressures. To this end, strategic patenting may result in the contravention of competition law as the use of patents may be seen as a strategic commercial decision taken to continue to earn high profits unduly or prevent the entry of competitive pressures in the market.

4. TRENDS IN PATENT APPLICATIONS BY MOLECULE AND MANUFACTURER

The patenting behaviour of pharmaceutical firms is an important first step to understand the commercial rationale pharmaceutical firms may have. This is particularly important in the

[38] In this regard, when there is generic competition, pharmaceutical companies have an incentive to produce differentiated (i.e., innovated) drugs for which they may enjoy patent protection.
[39] Gurgula, O. (2020). Strategic Patenting by Pharmaceutical Companies–Should Competition Law Intervene? *IIC-International Review of Intellectual Property and Competition Law*, *51*(9), 1062-1085.
[40] Bader, M. A., Gassmann, O., Ziegler, N., & Ruether, F. (2012). Getting the most out of your IP–patent management along its life cycle. *Drug discovery today*, *17*(7-8), 281-284.

pharmaceutical sector as high prices are often observed and attributed to the use of patents and strategic patent applications to limit competition in broader markets.

In assessing patent trends and behaviour in the South African pharmaceutical sector, we had regard to the three most prevalent diseases that create a significant burden on the health system and cause death in South Africa, namely, (i) HIV; (ii) TB and (iii) Diabetes. The information on diseases that have a significant contribution to South Africa's mortality rates – was obtained from Statistics South Africa ("StatsSA"[41]).

In terms of data, this research relied on both publicly [42] available information and data sourced from a private research firm (IQVIA) to conduct the analysis of the patent trends and behaviour. In addition, this research considered the diseases for which there is a higher number of drugs with patents. Based on these considerations, this research focused on drugs used to treat three diseases, namely (i) HIV); (ii) TB and (iii) Diabetes as noted above. [43] Information on the active ingredients and drug names was largely obtained from the essential medicines list (as published by WHO[44] and UKZN[45]) and other sources such as Medindia[46] and Medspal[47].

To identify whether the sampled drugs were protected by patents and thus susceptible to strategic patenting, this research used information from mainly two sources, namely (i) data from the Medicines Patents Pool ("MPP")[48] – which shows information on patented drugs across the globe; and (ii) data obtained from IQVIA – which contains the South Africa private sector pharmaceutical products patent data. The research also supplemented the data from IQVIA with the sample of drugs used in the public sector (as retrieved from the National Department of Health's "Master Health Product List") since most individuals with TB and HIV in South Africa access treatment from the public healthcare system[49].

The first part of the analysis considers the market structure landscape in terms of patent filings by assessing active and expired patents on molecules that treat the three diseases that form part of

---

[41] Statistics South Africa, 2021: Mortality and causes of death in South Africa: Findings from death notification. Available at: https://www.statssa.gov.za/publications/P03093/P030932017.pdf Accessed: 7 July 2022)
[42] Information on single exit prices for drugs – this was obtained from the National Department of Health (Pricing Committee).
[43] HIV has the highest number of drugs with patents and is also in the top 5 diseases that cause natural death in South Africa. TB is ranked number one in diseases that cause natural death in South Africa, and it is followed by diabetes at number two.
[44] WHO, 2021: Publications: Overview: WHO Model List of Essential Medicines for Children. Available at: https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.03 (Accessed: 7 July 2022)
[45] University of KwaZulu Natal, 2021: Pharmaceutical Services Essential Medicines List. Available at: http://www.kznhealth.gov.za/edl.htm (Accessed: 7 July 2022)
[46] Medindia, 2021. Drugs: Drug Information. Available at: https://www.medindia.net/doctors/drug_information/home.asp
[47] See: https://www.medspal.org/?page=1
[48] Medicines Patent Pool, 2022: Medicines Patent and Licence Database. Available at: https://www.medspal.org/?page=1 (Accessed: 07 July 2022)
[49] Naidoo, P., *et al.* 2017. "The South African Tuberculosis Care Cascade: Estimated Losses and Methodological Challenges". *The Journal of Infectious Diseases*, 216(S7): S702–13.

this research. This is to provide an overview of market shares and the concentration of patent filing activity by manufacturers. The second part of the analysis examines whether there is the existence of any form of potential strategic patent behaviour at the molecule level that may potentially have implications for competition. As discussed earlier in the research, patent abuse can take many forms. In this context, our approach in assessing the potential anti-competitive use of patents in the South African pharmaceutical sector, the research has considered evidence of (i) multiple patents filed for the same molecule and (ii) patents not being worked as required by the Patents Act[50]. To determine if a patent on a molecule is being worked, the research considered whether the molecule is registered with the South African Health Products Regulatory Authority (SAHPRA) and hence supplied in the market.[51] Given that the dataset relied upon does not include patent grant dates but patent expiry dates, the research estimated the patent grant dates based on the patent expiry date considering that a patent in South Africa is granted for a maximum of 20 years.

The following subsections provide an assessment of patent trends and behaviour at the manufacturer and molecule level.

4.1. Patent trends and behaviour at the manufacturer level

At the manufacturer level, the assessment had regard to two categories of patents on molecules by pharmaceutical manufacturers including the total number of (i) patents expired and (ii) patents that are currently in force. These categories of patents were segmented based on the diseases that are the focus of this research, namely Diabetes, HIV and TB. The analysis shows that from the three disease categories considered, there are fewer patents recorded in the TB and Diabetes markets when compared to HIV in the South African private sector. There is also the concentration and dominance of a few pharmaceutical groups in terms of patent filings.

Below we provide an assessment of patent filing activity at the manufacturer level for molecules that treat Diabetes, HIV and TB.

Diabetes

Diabetes is a chronic illness caused by the pancreas not producing enough insulin or the body not effectively using insulin. The global prevalence of diabetes in 2017 was about 8.8% and that is

[50] Section 56(2)(a) of the Patents Act addresses the abuse of patents where patent rights may be deemed to be abused, amongst other things, if: "*the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioners no satisfactory reason for such non-working*".

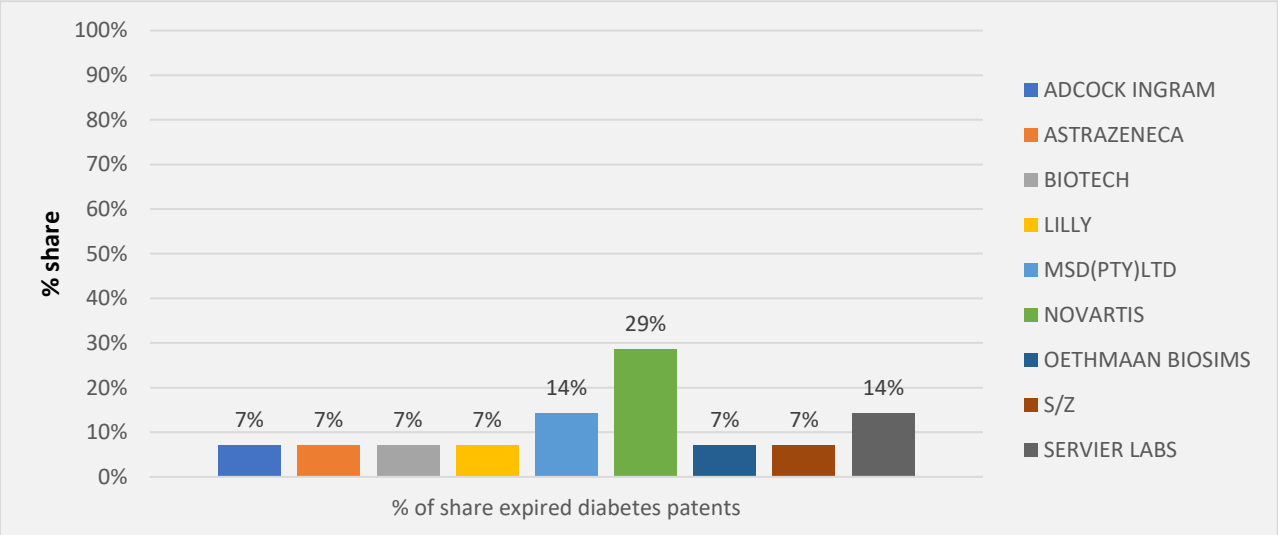
[51] Registered health products by SAHPRA can be sourced here: https://medapps.sahpra.org.za:6006/ . SAHPRA is, amongst other things, responsible for the licensing of manufacturers, wholesalers, and distributors of medicines and medical devices; radiation emitting devices and radioactive nuclides.

expected to increase significantly by 2045. Though not all countries are affected equally In South Africa, diabetes affects approximately 4.5 million people. The proportion of the adult population living with the condition is estimated at 12.8%. It's the leading cause of death among women in South Africa. In 2019, 89,834 people died of diabetes.[52] Likewise, not all countries have the same standards of care or costs for care. Norway, Switzerland, and the U.S. have some of the highest costs per person with diabetes. For example, in 2021, the US cost of treating diabetes averaged $11 779 compared to $1 700 incurred in South Africa over the same period.[53]

The South African oral anti-diabetes drug market is consolidated, with a few major manufacturers like Eli Lilly, AstraZeneca, Sanofi, and Janssen Pharmaceuticals having a global market presence.[54] There has been a total of 46 patents recorded on Diabetes molecules in the South African private sector market. Of this total number of patents, a total of 14 have already reached expiry, whilst 6 patents are still active in the market. The remaining bulk of the patents (26) have an unknown status.

The dataset shows that there are 9 manufacturers with patents for Diabetes molecules. As we demonstrate in **Figure 2** below, Novartis has the greatest number of Diabetes patents that have expired in the market with a 29% share, followed by MSD (Pty) Ltd and Servier Labs with a 14% share each. The remaining balance of expired patents in the Diabetes market is fairly distributed across 6 pharmaceutical groups (i.e., Adcock Ingram, AstraZeneca, Biotech, Lilly, OethMaan and S/Z) with each group having a 7% share of expired patents for specific Diabetes molecules.

Figure 2: Percentage share of expired Diabetes patents by manufacturer

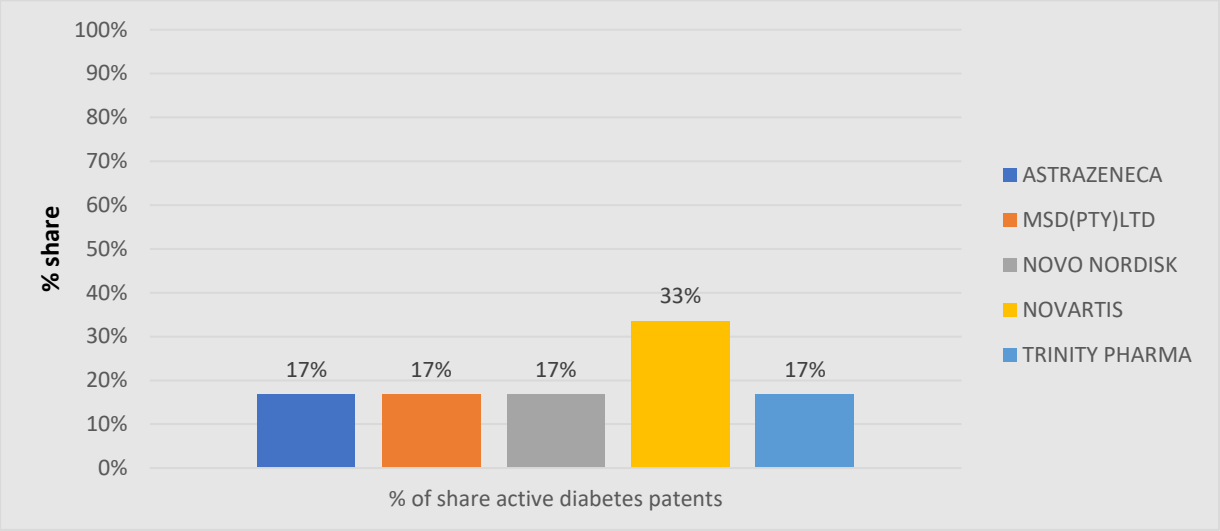


Source: Authors' analysis based on IQVIA data

[52] https://theconversation.com/our-research-shows-gaps-in-south-africas-diabetes-management-programme-160275 [accessed 31 October 2023]
[53] https://diabetesatlas.org/data/en/compare/185-211/idf-country-data-comparision.html [accessed 7 November 2023]
[54] https://www.mordorintelligence.com/industry-reports/south-africa-oral-anti-diabetic-drug-market [accessed 31 October 2023]

With respect to the total number of active patents on Diabetes molecules by manufacturer, it is apparent in **Figure 3** below that Novartis has a larger share of 33% in the market, whilst the remaining share is equitably spread amongst 4 pharmaceutical companies, namely AstraZeneca, MSD(PTY) LTD and Trinity Pharma with each group having 17% market share. This trend can partly be explained by the fact that 4 of these pharmaceutical groups with active Diabetes patents, namely, AstraZeneca, MSD (Pty) Ltd, Novo Nordisk and Novartis are the leading manufacturers when it comes to innovative diabetes medicines globally.[55]

Figure 3: Percentage share of active Diabetes patents by manufacturer



Source: Authors' analysis based on IQVIA data

In terms of the active Diabetes patents, Novartis also has 2 patents for Galvus and Jalra – both are oral antidiabetics used to treat type II diabetes. Both molecules have patents estimated to expire in 2026. The two other molecules which Novartis is supplying for the treatment of diabetes, Jalramet and Galvus met, had patents expiring in 2022. This means that for the particular oral antidiabetic drugs used in the treatment and management of diabetes, Novartis was able to extend its market exclusivity by another four years as a result of how the patent applications were made and granted in South Africa.

HIV

HIV remains one of the major global health crises. On 13 July 2023, the World Health Organization (WHO) reported that an estimated 39 million people were living with HIV at the end of 2022, two-thirds of whom (25.6 million) are in the African region. HIV is one of the leading causes of death globally, as in 2022, approximately 630 000 people died from HIV-related causes[56].

[55] Accessed at: https://www.fortunebusinessinsights.com/industry-reports/diabetes-drugs-market-100570 .
[56] WHO. 2023. "HIV and AIDS". Accessed at: https://www.who.int/news-room/fact-sheets/detail/hiv-aids

In South Africa, the prevalence of HIV is significantly high. A study published in 2021, recorded that more than 7.5 million people live with HIV, which makes South Africa one of the largest HIV epidemics in the world. Given that all people living with HIV in South Africa are eligible to commence with Anti-retroviral treatment ("ART") treatment regardless of age, CD4 cell count and clinical stage, there is an array of treatment types used for HIV[57].

The cost of HIV treatment in South Africa has substantially reduced over time owing to the interventions by the competition authorities by ensuring generic entry into the market. This was achieved through a settlement reached in 2003 with two manufacturers (GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI)) whose HIV drugs were under patent to allow generic manufacturers to use their patents to produce ART treatment[58]. Consequently, the availability of generic drugs in the South African market has resulted in price competition and a reduction in drug prices treating HIV[59]. For instance, the average cost of ART per patient per year in South Africa is estimated to be $249.15 for adults and about $284.10 for pediatric patients[60].

The main players in the HIV drugs markets globally are AbbVie, Boehringer Ingelheim, Bristrol-Myers Squibb Company, Cipla, F. Hoffmann-La Roche, Gilead Sciences, GSK, Johnson & Johnson, Merck & Co., and Teva Pharmaceuticals[61].

The research found that there are a total of 289 patents on HIV molecules in the South African private sector. Even though there is a large tail of patents (127 out of 289) whose duration has come to an end, there is still a considerable number of patents that are active in the market (119 out of 289). From the dataset, there is also a total of 43 patents lodged for HIV molecules where there is no information on their status (i.e., whether they have expired or are still in force).

---

[57] Kim, H. *et al*. 2021. "Beyond HIV prevalence: identifying people living with HIV within underserved areas in South Africa". BMJ Global Health 2021; 6:e004089. doi:10.1136/bmjgh-2020-004089

[58] As part of the settlement agreement concluded with GSK and BI, they agreed to: (i) grant licenses to generic manufacturers; (ii) permit the licensees to export the relevant ARV medicines to sub-Saharan African countries; (iii) where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only (provided all the regulatory approvals were obtained); (iv) permit licensees to combine the relevant ARV's with other ARV's medicines; and (v)not require royalties in excess of 5% of the net sales of the relevant ARVs (see: https://unctad.org/system/files/non-official-document/ciclp18th_cont_South_Africa_II.pdf and Hazel Tau & others v. GlaxoSmithKline, Boehringer Ingelheim & others. 2002. South African Competition Commission, Competition Commission Case No. 2002Sep226.

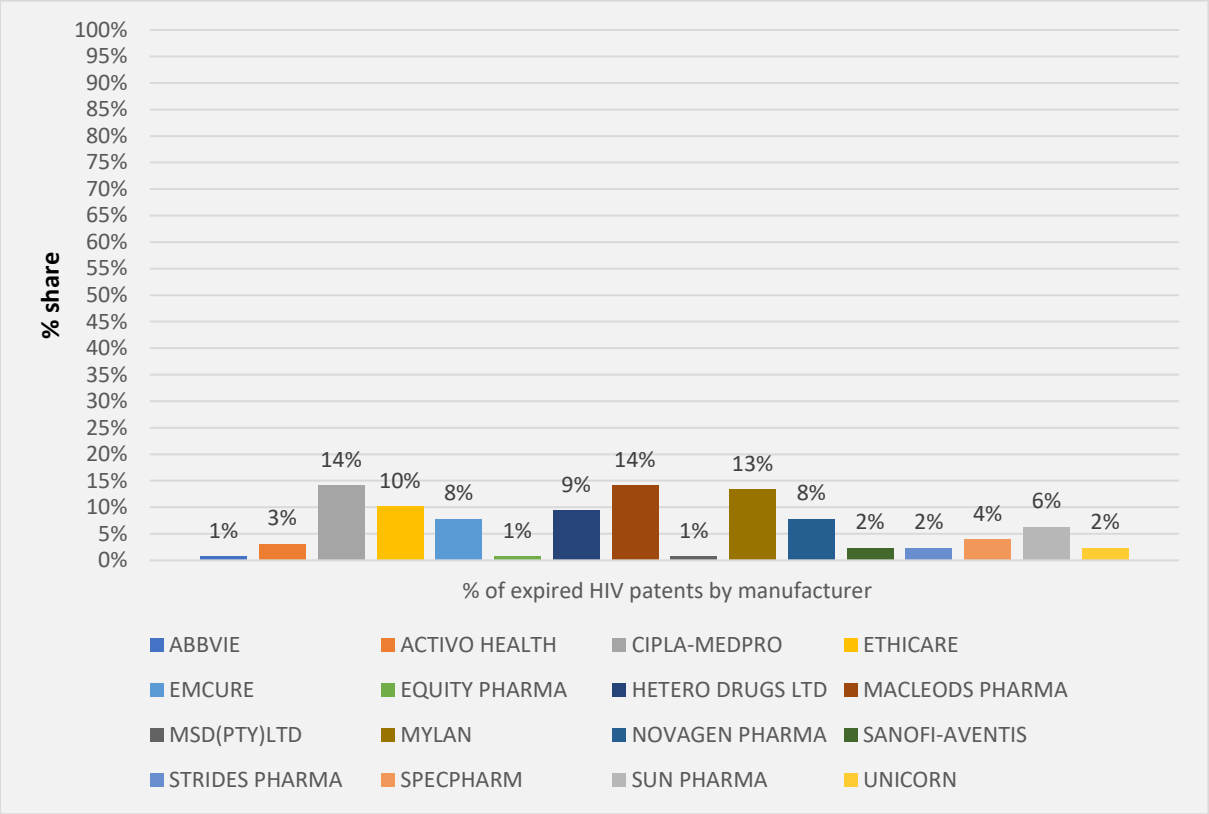
[59] South African Government. 2010. "*Massive reduction in ARV prices*". Accessed at: https://www.gov.za/massive-reduction-arv-prices

[60] Meyer-RathI, G. *et al*. 2019. "The per-patient costs of HIV services in South Africa: Systematic review and application in the South African HIV Investment Case". *PLoS One*;14(2): e0210497. doi:10.1371/journal.pone.0210497. PMID: 30807573; PMCID: PMC6391029.

[61] Accessed at: https://www.alliedmarketresearch.com/hiv-drugs-market

In the case of expired patents on HIV molecules, there is a total of 16 pharmaceutical groups that no longer have patent protection for HIV molecules in the private sector[62]. As shown in **Figure 4** below, 7 pharmaceutical groups had more than 10 patents that have expired during the period under review, namely: Cipla-Medpro (14% share); Macleods Pharma (14% share); Mylan (13% share); Ethicare (10% share); Hetero Drugs Ltd (9% share); Emcure (8% share); and Novagen Pharma (8% share).

Figure 4: Percentage share of expired HIV patents by manufacturer

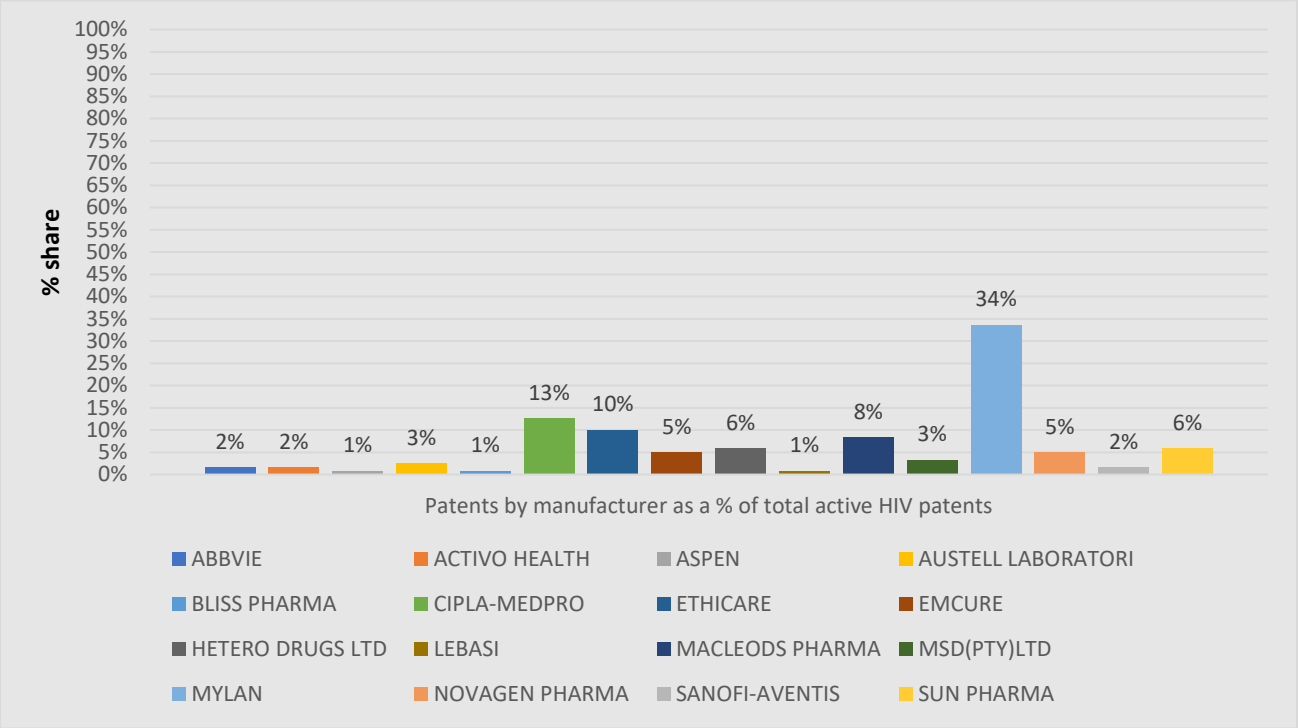


Source: Authors' analysis based on IQVIA data

As with active patents on HIV molecules, there appears to be a clear disjuncture in the total number of patents lodged by pharmaceutical groups in the private sector market. While there are several manufacturers with active patents on HIV molecules, it is notable in **Figure 5** below that some groups have a larger share of active patents. The top 3 pharmaceutical groups with the most active patents in this market are Mylan (34%), Cipla Medpro (13%) and Ethicare (10%).

[62] The HIV molecules with expired patents are: 3TC; Arion, Aspen Abacavir, Aspen Lamivudine, Aspen Lamzid , Aspen Tenofoviratenef, Atreslawin , Bavir; Cagol, Cipla-Abacavir; Cipla-Duovir; Citenvir; Combivir; Dalidou, Deladex; Didivir; Divudine; Dumiva; Eflaten; Eftenem; Elteno; Emcovir; Emten; Emtroc; Heftenam; Hetacav; Hetbaclam; Hetemcit; Heteruam; Invetron; Isentress; Kavideza; Kavimun; Kavimun Paed; Kavmyl; Lopimune; Mivuten; Norvir; Quadrimune; Riatem; Ricovir; Rilovia; Riovex; Ritoataz; Rizene; Sonke Abacavir; Sonke-Lamivu/Zidov; Sonke-Lamivudine; Sonke-Tenofovir; Tabex; Tafbin; Tarito; Teerenz; Telzir; Tencitab; Tenemcom; Tenemine; Tenofovi; Trenvir; Triemta; Triolar, Tripavir Trivage; Truno; Truvada; Tyricten, Videx EC; Vidoteg; Viread; Zadurna; Zatonav; Zefin; Zenfar and Ziagen.

Figure 5: Percentage share of active HIV patents by manufacturer



Source: Authors' analysis based on IQVIA data

In the public sector, the drugs used to treat HIV are supplied through a tender process. The research found that there are about 10 single-use drugs[63]. Most of these molecules offered in the public sector no longer have patent protection. As shown in **Table 1** below, there are 3 single-use drugs (Raltegravir, Tenofovir and Atazanavir) where there is only one supplier. Of these 3 drugs with one supplier in the market, the research found only 1 molecule, namely Raltegravir which is supplied by MSD (Pty) Ltd was still under patent until 2025.

Table 1: List of single-use HIV drugs supplied in the public sector

Molecule	Manufacturer/Supplier	No. of suppliers	Patent expiry date
Single use drugs			
Raltegravir	MSD (Pty) Ltd	1	2025
Lamivudine	Adcock Ingram Healthcare (Pty) Ltd and Aurobindo Pharma (Pty) Ltd	2	2010
Tenofovir	Adcock Ingram Healthcare (Pty) Ltd	1	2010
Zidovudine	Adcock Ingram Healthcare (Pty) Ltd and Viatris Healthcare (Pty) Ltd ta Mylan (Pty) Ltd	2	2010
Efavirenz	Adcock Ingram Healthcare (Pty) Ltd, Pharmacare Limited and Viatris Healthcare (Pty) Ltd ta Mylan (Pty) Ltd	3	2010
Nevirapine	Adcock Ingram Healthcare (Pty) Ltd and Cipla Medpro SA (Pty) Ltd	2	2010
Dolutegravir	Hetero Drugs SA (Pty) Ltd, Viatris Healthcare (Pty) Ltd ta Mylan (Pty) Ltd and Sonke Pharmaceuticals (Pty) Ltd	3	2026

[63] These include: Raltegravir, Lamivudine, Tenofovir, Zidovudine, Efavirenz, Nevirapine, Dolutegravir, Abacavir, Atazanavir and Ritonavir.

Molecule	Manufacturer/Supplier	No. of suppliers	Patent expiry date
Abacavir	Viatris Healthcare (Pty) Ltd ta Mylan (Pty) Ltd, Pharmacare Limited and Hetero Drugs SA (Pty) Ltd	3	2031
Atazanavir	Aurobindo Pharma (Pty) Ltd	1	2004
Ritonavir	Hetero Drugs SA (Pty) Ltd and ABBVIE (PTY) LTD	2	2017

Source: Authors' analysis based on IQVIA, National Department of Health Current Master Health Product List dated 1 Aug 2023, Google Patent Search and Desktop Research

The public sector also makes use of 9 combination drugs in the treatment of HIV.[64] The vast majority of these drugs are supplied by off patent and generic manufacturers (such as Cipla Medpro SA, and the local entity Sonke Pharmaceuticals) are also active in this space. There are two combination drugs (Darunavir and Ritonavir, and Atazanavir and Ritonavir) that are supplied by a single manufacturer. From these two HIV combination drugs with only one manufacturer or supplier, Ritonavir and Atazanavir molecules are off patent, whilst Darunavir molecule has also recently lost patent protection on 16 May 2023.[65] Based on the above, there appears to be generic competition given the presence of multiple suppliers supplying the same molecular products in the market. Most molecules supplied in the public sector also seem to have lost patent protection, providing scope for generic entry and competition in this market going forward. The implication of this from a competition perspective is that prices for HIV treatment drugs should reflect the generic competition observed from the patent applications.

Tuberculosis

In 2023, the WHO reported that TB is the second leading infectious disease that causes death globally. The prevalence of TB is also growing worldwide with an estimated 10.6 million people falling ill with TB in 2021[66]. South Africa on the other hand has one of the highest TB burdens globally. Notably, the country is among the top 30 list of countries that are heavily burdened by this disease on the global front[67]. In 2019, the incidence of TB was estimated to be 615 per 100,000 population in South Africa[68].

[64] These drugs include (i) Tenofovir, Lamivudine, Dolutegravir; (ii) Tenofovir, Emtricitabine, Efavirenz; (iii) Darunavir, Ritonavir; (iv) Lamivudine, Abacavir; (v) Lopinavir, Ritonavir; (vi) Atazanavir, Ritonavir; (vii) Tenofovir, Emtricitabine; (viii) Lamivudine, Abacavir, Dolutegravir; and (ix) Zidovudine, Lamivudine.

[65] See: https://www.medspal.org/?product%5B%5D=Darunavir+300+mg&countries%5B%5D=South+Africa&disease_area%5B%5D=HIV&page=1

[66] WHO. 2023. "Tuberculosis". Accessed at: https://www.who.int/news-room/fact-sheets/detail/tuberculosis#:~:text=Worldwide%2C%20TB%20is%20the%2013th,all%20countries%20and%20age%20groups.

[67] South African Medical Research Council. 2021. "The First South African National TB Prevalence Survey gives a clearer picture of the epidemic". Accessed at: https://www.samrc.ac.za/press-releases/first-south-african-national-tb-prevalence-survey-gives-clearer-picture-epidemic

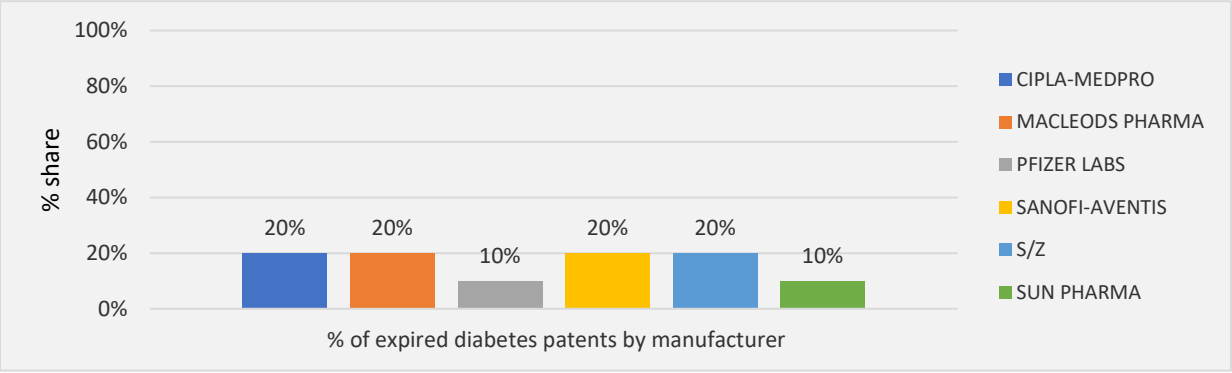
[68] Conan N. *et al*. 2022. Prevalence of TB and health-seeking behaviour. *The International Journal of Tuberculosis and Lung Disease*, 26(5):463-465. doi: 10.5588/ijtld.22.0001. PMID: 35505477; PMCID: PMC9067428.

TB is treated with a combination of medicines which include antibiotics that reduce the bacterial load in the lungs and may also serve to reduce the probability of transmission[69]. It is also well accepted that antituberculosis regimens (i.e., TB treatment) has a positive clinical efficacy[70]. Given that the public sector facilities provide healthcare services to the majority of the population in South Africa, the more serious form of TB disease is tested and treated in the public sector. This is affirmed by estimates from academic literature that about 80% to 90% of all first-line TB treatment is provided by the public sector in South Africa[71].

The major players in the TB treatment drugs market globally are Lupin, Sanofi, Pfizer, Fresenius SE & Co., Johnson & Johnson, Teva Pharmaceuticals, Novartis, ANI Pharmaceuticals, Otsuka Pharmaceuticals Co., and MacLeods Pharmaceuticals[72].

The research uncovered a total of 37 patents on TB molecules by manufacturers filed in the South African private sector market. Of these total patents, there are 10 patents on specific TB molecules of which pharmaceutical groups have exhausted their exclusive patent rights, whilst for a large proportion of these patents (27), their status remains unknown. Given that most patents on TB molecules in the dataset have unknown status, this research has only considered trends with respect to expired patents to provide insights on historic patent filing activity in this market segment. As depicted in Figure 6 below, the leading pharmaceutical groups in terms of expired patents are Cipla Medpro, Macleods Pharma, Sanofi-Aventis, and S/Z with a 20% share each in the TB market. Pfizer and Sun Pharma make up the remaining 20% share of the market.

Figure 6: Percentage share of expired TB patents by manufacturer



Source: Authors' analysis based on IQVIA data

[69] Sotgiu, G. *et al.* 2015. Tuberculosis treatment and drug regimens. *Cold Spring Harbor Perspectives in Medicine*,5(5):a017822. doi: 10.1101/cshperspect.a017822. PMID: 25573773; PMCID: PMC4448591.
[70] Rabahi, M. F, *et al.* 2017. Tuberculosis treatment. *Brazilian Journal of Pulmonology*, 43(6):472-486. doi: 10.1590/S1806-37562016000000388..
[71] Benade M, *et al.* 2022. Reduction in initiations of drug-sensitive tuberculosis treatment in South Africa during the COVID-19 pandemic: Analysis of retrospective, facility-level data. *PLOS Global Public Health*, 11;2(10):e0000559. doi: 10.1371/journal.pgph.0000559. PMID: 36962535; PMCID: PMC10021649.
[72] Accessed at: https://www.alliedmarketresearch.com/tuberculosis-treatment-drugs-market-A13238

Conclusion on patent trends and behaviour at the manufacturer level

The analysis of patent trends and behaviour at the manufacturer level demonstrates the increasing use of patents and reliance by a few global firms on intellectual property tools to safeguard their inventions, thereby preserving their competitive positioning in the market. The research found that Novartis is a significant pharmaceutical group in terms of the overall patent filings for molecules that treat Diabetes, whilst for HIV and TB molecules, respectively, Mylan and Sanofi-Aventis are the largest groups. We now turn to discuss our findings on patent trends and behaviour at the molecule level to show the existence of any form of potential strategic patenting by pharmaceutical groups.

4.2. Patent trends and behaviour at molecule level

As outlined in **Section 3** above, patent thickets are a form of strategic patenting that refer to the filing of multiple patent applications[73] for the same medicine often with overlapping claims on new formulations, processes, additional pharmaceutical indications, and forms.[74] The approach adopted by this research is to focus on any evidence of multiple patents lodged for the same molecule by a manufacturer as an indicator of possible patent thicketing behaviour. The analysis is, however, conducted with the caveat that the dataset relied upon does not allow for determination of whether the patents filed on the same molecule are on the formulation, process, and other additional pharmaceutical indications.

Patent thickets on HIV drugs

With respect to expired patents in the HIV market, the research found 37 molecules[75] in the private sector where there is more than one patent that was filed by the same pharmaceutical group, as illustrated in **Figure 7** below. Of these patents on HIV molecules that have expired in the private sector above, 13 manufacturers had more than one patent on an HIV molecule[76]. This provides some indication of multiple patent applications having been made by these manufacturers.

---

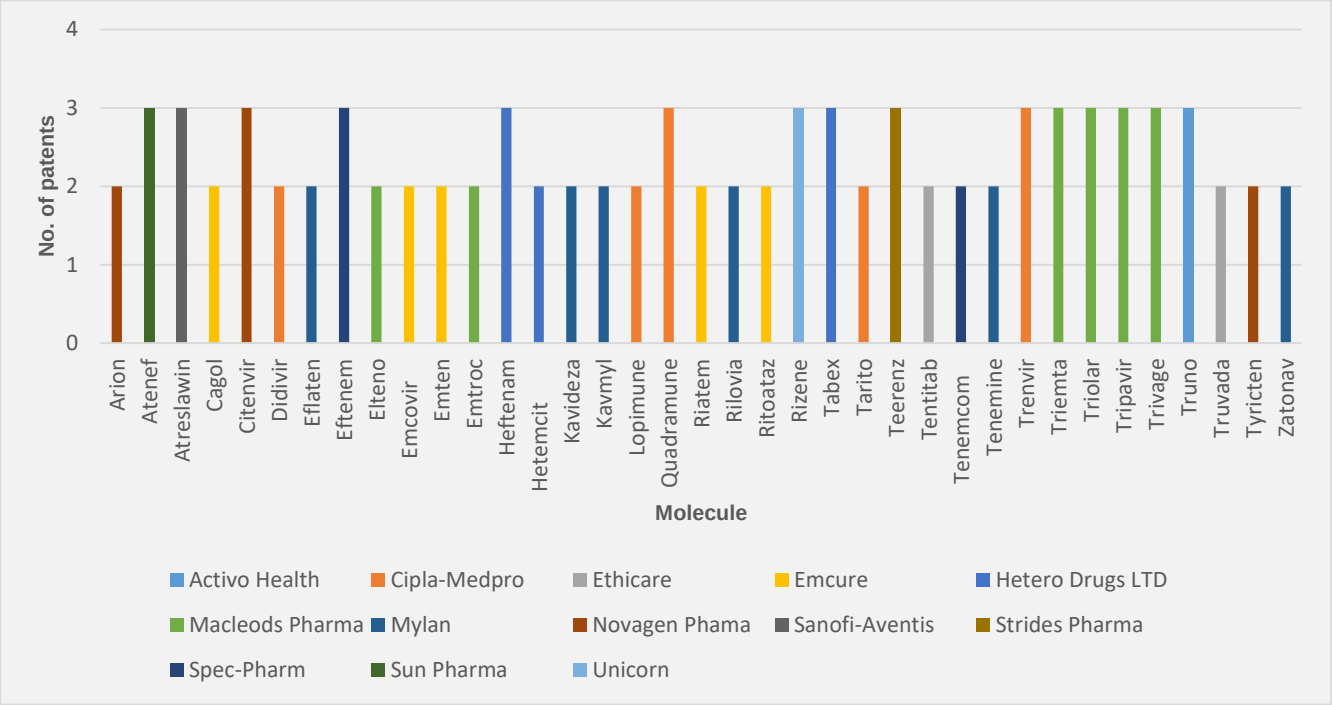
[73] These are sometimes referred to as secondary patents (EC, 2009)

[74] European Commission, 2009: Pharmaceutical Market Inquiry. Available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (Accessed: 04 July 2022)

[75] These molecules are Arion; Atenef; Atreslawin; Cagol; Citenvir; Didivir; Eflaten; Eftenem; Elteno; Emcovir; Emten; Emtroc; Heftenam; Hetemcit; Kavideza; Kavmyl; Lopimune, Quadrimune; Riatem; Rilovia; Ritoataz; Rizene; Tabex; Tarito; Teerenz; Tencitab; Tenemcom; Tenemine; Trenvir; Triemta; Triolar; Tripavir; Trivage; Truno; Truvada; Tyricten and Zatonav

[76] (i) Activo Health on Truno; (ii) Cipla Medpro on Didivir, Lopimune, Qadrimune, Tarito and Trenvir; (iii) Ethicare on Tencitab and Truvada; (iv) Emcure on Cagol, Emcovir, Emten, Riatem and Ritoataz; (v) Hetero Drugs Ltd on Heftenam, Hetemcit and Tabex; (vi) Macleods Pharma on Elteno, Emtroc, Triemta, Triolar, Tripavir and Trivage; (vii) Mylan on Eflaten, Kavideza, Kavmyl, Rilovia, Tenemine and Zatonav; (viii) Novagen Pharma on Arion, Citenvir and Tyricten; (ix) Sanofi-Aventis on Atreslawin; (x) Strides Pharma on Teerenz; (xi) Specpharm on Eftenem and Tenemcom; (xii) Sun Pharma on Atenef; and (xiii) Unicorn on Rizene

Figure 7: Multiple manufacturer patent applications on expired patents for HIV molecules

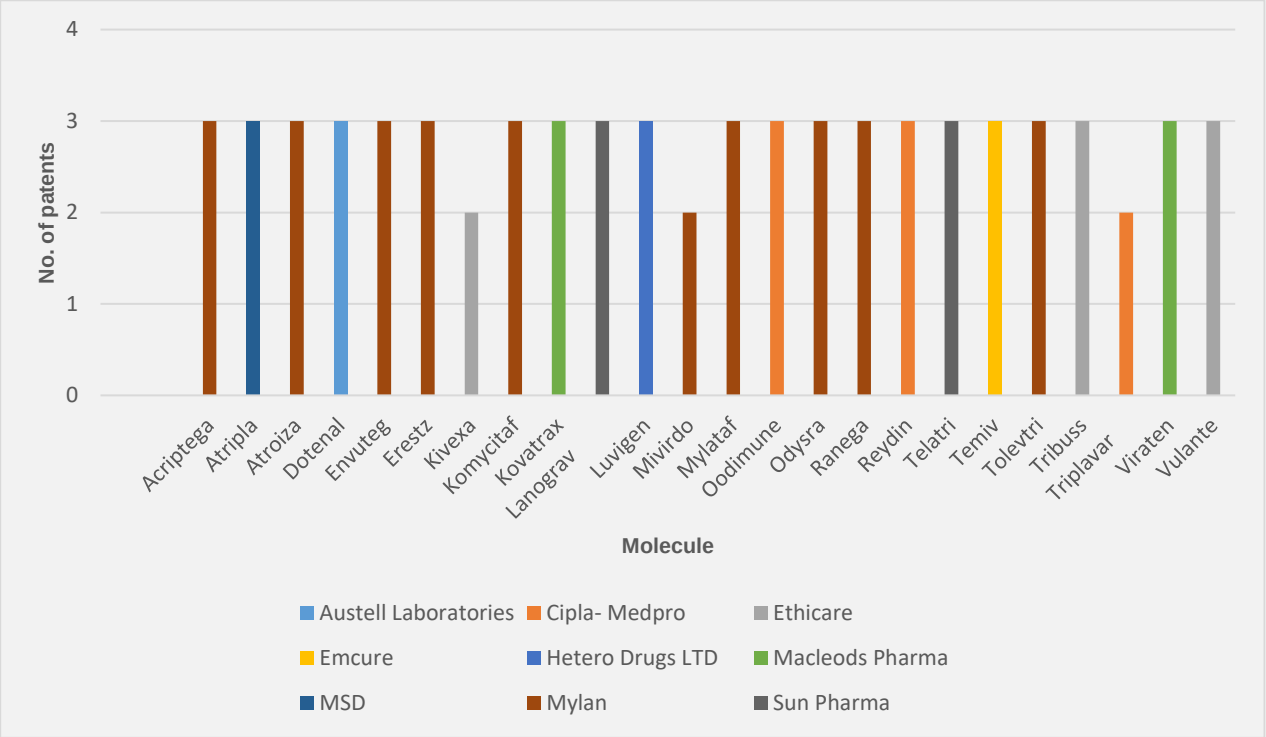


Source: Authors' analysis based on IQVIA data

A set of potentially overlapping patent rights (patent thickets) that are currently active in the HIV market were also detected on 24 molecules in the private sector[77] as shown in **Figure 8** below. Of these patents on HIV molecules that are in force, the following manufacturers have more than one active patent on an HIV molecule: (i) AustellLaboratries on Donatel; (ii) Cipla Medpro on Odimune, Reydin and Triplavar; (iii) Ethicare on Kivexa, Tribuss and Vulante; (iv) Emcure on Temiv; (v) Hetero Drugs Ltd on Luvigen; (vi) Macleods Pharma on Kovatrax and Viraten; (vii) MSD (Pty) Ltd on Atripla; (viii) Mylan on Acriptega, Atroiza, Envuteg, Erestz, Komycitaf, Mivirdo, Mylataf, Odystra, Ranega and Tolevtri; and (ix) Sun Pharma on Lanograv and Telatri.

[77] These molecules are Acriptega; Atripla; Atroiza; Dotenal; Envuteg; Erestz; Kivexa; Komycitaf; Kovatrax; Lanograv; Luvigen; Mivirdo; Mylataf; Odimune; Odystra; Ranega; Reydin; Telatri; Temiv; Tolevtri; Tribuss, Triplavar; Viraten; and Vulante.

Figure 8: Multiple patent applications on active patents for HIV molecules



Source: Authors' analysis based on IQVIA data

The analysis above shows that the conduct of filing multiple patents on the same molecule in the HIV market is commonly practiced by Mylan, which has a substantial number of potentially overlapping patents (patent thickets) on HIV molecules that are still in force (i.e., 10 out of a total of 24). This trend is consistent with the finding in the section above that Mylan is the leading market player in terms of active patents recorded in the HIV market in the South African pharmaceutical sector.

This research also considered whether patents granted are being worked (i.e., supplied in the market) as required by the Patents Act. **Table 2** below demonstrates that all the molecules with active patents in the HIV market (a total of 24) are registered with SAHPRA.

Table 2: Analysis of patent use in the HIV market

Molecule	Manufacturer	SAHPRA registration (Yes/No)	SAHPRA registration date	Patent expiry date	Estimated patent grant date
Acriptega	Mylan Pharmaceuticals	Yes	2018/08/31	2032	2012
Atripla	MSD (Pty) Ltd	Yes	2010/01/10	2024	2004
Atroiza	Mylan Pharmaceuticals	Yes	2012/07/06	2024	2004
Dotenal	Austell Pharmaceuticals	Yes	2021/07/09	2032	2012
Envuteg	Mylan Pharmaceuticals	Yes	2021/03/08	2031	2011
Vulante	Ethicare	Yes	2018/10/10	2031	2011

Molecule	Manufacturer	SAHPRA registration (Yes/No)	SAHPRA registration date	Patent expiry date	Estimated patent grant date
Erestz	Mylan Pharmaceuticals	Yes	N/A	2026	2006
Kivexa	Ethicare	Yes	2005/09/23	2026	2006
Komycitaf	Mylan Pharmaceuticals	Yes	2021/01/21	2031	2011
Kovatrax	Macleods Pharmaceuticals	Yes	2018/10/10	2031	2011
Lanograv	Sun Pharma	Yes	2018/10/10	2032	2012
Viraten	Macleods Pharmaceuticals	Yes	2018/10/10	2032	2012
Triplavar	Cipla Medpro	Yes	2011/04/15	2026	2006
Tribuss	Pharmacare Limited	Yes	2011/11/25	2024	2004
Tolevtri	Mylan Pharmaceuticals	Yes	2021/03/08	2031	2011
Temiv	Emcure	Yes	2018/10/10	2031	2011
Telatri	Sun Pharma	Yes	2018/10/10	2032	2012
Reydin	Cipla Medpro	Yes	2018/08/31	2032	2012
Ranega	Mylan Pharmaceuticals	Yes	2018/08/31	2032	2012
Odystra	Mylan Pharmaceuticals	Yes	2018/08/31	2032	2012
Odimune	Cipla Medpro	Yes	2012/09/02	2024	2004
Mylataf	Mylan Pharmaceuticals	Yes	2021/01/26	2032	2012
Mivirdo	Mylan	Yes	2013/10/10	2026	2006
Luvigen	Hetergo Drugs South Africa	Yes	2018/10/10	2031	2011

Source: Authors' analysis based on SAHPRA, Medicine Price Registry and IQVIA data

Patent thickets on TB drugs

TB drug manufacturers are largely granted patents related to a single drug on, among other factors, the following: (i) compounds; (ii) manufacturing process and (iii) combinations. From the sample of 9 molecules with expired patents in the TB market, the research found only one molecule in the private sector, namely, Cotrizid by Cipla Medpro with more than one patent lodged. This suggests that there may have been a patent thicketing tactic by Cipla Medpro for the Cotrizid molecule. However, this molecule is currently supplied in the market as it was registered with SAHPRA on 18 February 2020, even though its patent expired in 1981.[78]

[78] See: https://medapps.sahpra.org.za:6006/Home/Details/?id=CfDJ8JkvJohYLuhBr10wTCe_OehKRiuuFvBK-yD4RNatdPMX8raiFLXSpdIZaO-Pef20RCzcXl6YBX9mr_jauHZwo-EQ6ZpARUonWfCb-HIcGeclr7uqwpWUMMPzkw5Z7cudNA

In terms of drugs in circulation in the public sector, a little more variety is observed as shown in **Table 3** below. As the research is limited to publicly available information, it is clear that in terms of the earlier TB treatment (single-use drugs and combinations), the majority of suppliers supplying the drugs in South Africa are doing so off-patent. Drugs which appear to be still under active patents are those used to treat multidrug resistant TB.

Table 3: List of TB drugs supplied in the public sector

Molecule	Manufacturer/Supplier	Patent expiry date
Single-use drugs		
Ethambutol	Sandoz SA (Pty) Ltd	1993
Rifampicin	Sandoz SA (Pty) Ltd	1981
Isoniazid	Viatris Healthcare (Pty) Ltd ta Mylan (Pty) Ltd	1981
Pyrazinamide	Macleods Pharmaceuticals SA (Pty) Ltd	-
Combination drugs		
Risopet (rifampicin, ethambutol, isoniazide & pyrazinamide)	Pharma Dynamics (pty) Ltd	1996
Rifinah (isoniazid & rifampicin)	Sanofi-Aventis SA (Pty) Ltd	2002
Co-Afaris Paed (Rifampicin, isoniazid & pyrazinamide)	Macleods Pharmaceuticals SA (Pty) Ltd	-
Afaris FC (Rifampicin & Isoniazid)	Macleods Pharmaceuticals SA (Pty) Ltd	-
MDR (multi-drug resistant)		
Ethionamide 250mg	Macleods Pharmaceuticals SA (Pty) Ltd	2023
Linezolid 600mg	Soigner Pharma, Cipla, Leeford (originator Pfizer)	2014
Delamanid 50mg	Otsuka Pharmaceuticals	2031
Levofloxacin	Austell Pharmaceuticals (Pty) Ltd	2022
Clofecin 100mg	Iveon Laboratories limited	-
Bedaquiline 100mg	Johnson & Johnson	2025
Terizidone 250mg	Macleods Pharmaceuticals SA (Pty) Ltd	2022
Moxifloxacin 400mg	Macleods Pharmaceuticals SA (Pty) Ltd	2019

Source: Authors' analysis based on IQVIA, National Department of Health Current Master Health Product List dated 1 Aug 2023, Google Patent Search, SAHPRA and Desktop Research

Data from MedsPaL shows that two new TB drugs – Bedaquiline and Delamanid are subject to several patent applications in South Africa. Specifically, for Delamanid, a base patent for both for 25mg and 50mg was granted in 2005 and expired in 2023. This was followed by a new use patent for the treatment of TB in 2006 which was withdrawn. Subsequently, there was two new formulation patents – Delamanid compositions (2007) and Delamanid in combination with other TB drugs (2008). The fifth patent was granted in 2012 for 'Delamanid intermediate compounds' and expires in 2031, more than seven years after the base patent expired in 2023.

Further, five different patents on Bedaquiline were granted. The base patent was granted in 2005 and will expire in 2025. Two so-called 'new use' patents were granted in 2006 (for the treatment of DR-TB) and 2007 (for the treatment of latent TB). A process patent (2007) and a new formulation patent (2009) were also granted – the latter expiring in 2029, four years after the base patent. New

formulation patents are mere reformulations of existing drugs and contain no new active pharmaceutical ingredient. Argentina, for example, does not grant such new formulation patents. India only grants them when they provide a therapeutic benefit.[79]

Based on the patent filing behaviour on the Bedaquiline molecule and non-use of the patent in South Africa, the competition authorities recently launched an investigation of exclusionary conduct and excessive pricing by Johnson & Johnson in the provision of the Bedaquiline drug in the market[80]. Following the initiation of this investigation, Johnson & Johnson announced that it will no longer enforce secondary patents on Bedaquiline in low- and middle-income countries, including South Africa.[81] This has effectively paved the way for generic versions of this key drug to enter markets at an affordable level, but in the short-term has resulted in a 45% price reduction negotiated by the National Department of Health.

This section has shown that for the TB drugs used in the public sector, there is a potential for patent thickets observed with secondary patent applications adding the effective patent protection period. Secondary patents like these eight patents on Bedaquiline and Delamanid often delay generic competition. Due to this lack of competition the prices of medicines in South Africa are often higher than prices for the same medicines in countries with laws that restrict secondary patenting.

Diabetes drugs

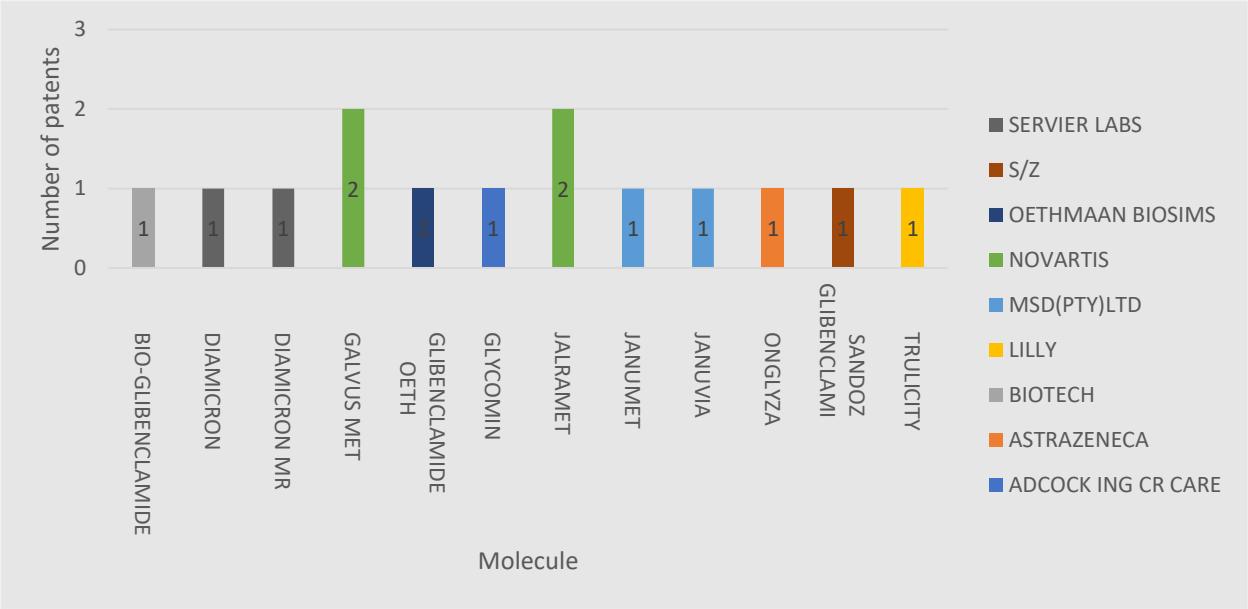
In terms of patents that have already expired, we note an insignificant number of Diabetes molecules (2 out of a total of 12) where there is a record of more than one patent previously filed for the same molecule as demonstrated in the **Figure 9** below. These molecules are Galvus Met and Jalramet which are manufactured by Novartis. No potential patent thicketing was observed for Diabetes molecules with active patents.

[79] https://www.spotlightnsp.co.za/2016/10/13/ten-patents-two-tb-drugs/

[80] See: https://www.compcom.co.za/wp-content/uploads/2023/09/Media-Statement-Commission-investigates-Johnson-Johnson-15-September-2023.pdf

[81] https://www.jnj.com/johnson-johnson-confirms-intent-not-to-enforce-patents-for-sirturo-bedaquiline-for-the-treatment-of-multidrug-resistant-tuberculosis-in-134-low-and-middle-income-countries

Figure 9: Multiple patent applications on expired patents for Diabetes molecules



Source: Authors' analysis based on IQVIA data

Conclusion on potential patent thicket strategy

The evidence presented above points to the possible practice of patent thicketing in the South African pharmaceutical sector, where multiple patents are filed by manufacturers on the same molecule. This is the case particularly in the HIV market, as the assessment shows a low prevalence of patent thickets on TB and Diabetes molecules. However, it is observable for some of the TB drugs (i.e., Delamanid and Bedaquiline), particularly used in the public sector, that patent thickets manifest in the form of secondary patent applications which have an effect of extending the patent protection period. From a competition standpoint, possible patent thicketing behaviour in the HIV and TB markets, which serves to extend the exclusivity of the drugs beyond the end of the initial patents, is likely to delay or prevent generic entry, leading to exorbitant prices for these drugs due to lack of competition.

5. CONCLUSION

This paper has considered the trends in patent applications for pharmaceutical drugs used to treat Diabetes, TB, and HIV, which are three chronic diseases with high prevalence and cause death in South Africa. The first part of the analysis considered the market structure landscape in terms of patent filings by assessing active and expired patents on molecules that treat the three diseases. This was to provide an overview of patent filing activity by pharmaceutical manufacturers. The second part of the analysis examined whether there is existence of any form of strategic patent behaviour at molecule level that may potentially have implications on competition.

The research finds the following:

Diabetes

In the Diabetes market, the research found a trivial number of patents active on molecules which account for 13% (i.e., 6 out of a total of 46 patents recorded in the private sector). At the manufacturer level, Novartis is found to be a significant player as reflected by their share of active patents for molecules treating Diabetes. Some limited evidence of patent thicketing through multiple patents on molecules was found for expired patents but none on active patents.

HIV

For molecules that treat HIV, the research revealed a substantial number of patent applications at the manufacturer in the private sector when compared to the Diabetes and TB markets. The research also found that about 41% (i.e., 119 out of a total of 289 patents lodged in the private sector) of these patents are still in force in the market.

In terms of the share of total patent filings (i.e., expired, and active patents), the research found Mylan to be a leading market player for drugs supplied in the private sector. It is notable from the research that there is likely to be generic competition, as suppliers to the state comprise both global and local generic manufacturers. Drugs supplied in the public sector are also mostly by off patent manufacturers.

At the molecule level, the research provided evidence of potential current and historic patent thickets on molecules that treat HIV. This is consistent with the evidence presented in the research that the HIV segment appears to be where patent filing activity is taking place when considering the three diseases that cause a burden on the healthcare system in South Africa.

TB

In the TB market, on aggregate (including expired patents and those with unknown status) it appeared that Sanofi-Aventis has a larger share in terms of overall patent filings in the private sector. For drugs in circulation in the public sector, a little more variety was observed in the analysis, where it was found that with respect to single-use and combination drugs that treat TB, most suppliers supplying these drugs in South Africa are doing so off-patent. The research, however, found multidrug resistant TB drugs to be the ones currently with active patents in the market and in some instances, multiple patent applications being made by manufacturers.

At the molecule level, the research also revealed evidence of potential patent thickets, in the form of secondary patent applications. This conduct that has necessitated interventions by competition authorities has been observed for specific drugs used in the public sector.

Having broadly analysed the trends and behaviour in patent applications, the implications of this research are two-fold. One, from a policy perspective, the implementation of the TRIPS flexibilities would enable the implementation of a more substantive and rigorous patent system. Under the current South African patent system, the novelty or inventive merit of the invention is not substantively examined. The system fundamentally misses out on protecting patents for a set period only after the examination of the patentability of the invention. Our view is consistent with the views of several industry advocacy groups[82]. To this end, a substantive search and examination patent system will be part of the solution.

Two, from a competition law and enforcement standpoint, the research has shown that the conduct by pharmaceutical firms in terms of patent filings may potentially raise competition concerns. Therefore, competition law and enforcement, has a role to play in addressing competition issues arising from strategic patenting conduct by pharmaceutical firms. Specifically, potential abuse of market power can be addressed by the Competition Act, through enforcement interventions against exploitative and exclusionary conduct by firms. This has been recently done by competition authorities in the case of Johnson and Johnson (Bedaquiline).

-End-

[82] See: https://www.cansa.org.za/files/2015/06/Fix-Patent-Laws-Briefer.pdf ; https://section27.org.za/2022/06/ftpl-patent-law-reform-june-2022/ ; https://www.fixthepatentlaws.org/the-time-to-fix-south-africas-patent-laws-is-now/