IN THE COURT OF THE COMMISSIONER OF PATENTS
FOR THE REPUBLIC OF SOUTH AFRICA

Case No.: Patent Nos. 2007/00601;
2008/09290; 2011/01097; 2012/00722;
2013/01419; 2014/06233; 2016/06418

In the application for admission as *amici curiae* of –

TREATMENT ACTION CAMPAIGN NPC	First Applicant
MÉDECINS SANS FRONTIÈRES SOUTHERN AFRICA NPC	Second Applicant

In re: the matter between –

CHERI NEL	First Applicant
CYSTIC FIBROSIS ASSOCIATION (CENTRAL REGION)	Second Applicant

and

VERTEX PHARMACEUTICALS INC.	Respondent

SUPPORTING AFFIDAVIT

I, the undersigned,

ANDISIWE CANDICE SEHOMA

do hereby state the following under oath:

1 I am an adult female, employed as the Access Campaign Advocacy Advisor at Médecins Sans Frontières Southern Africa NPC ("MSFSA").

2 MSFSA is a non-profit organisation, and is registered as a non-profit company (registration no. 2007/008324/08). Its head office is located on the 9th floor of Zurich House, 70 Fox St, Marshalltown, Johannesburg.

3 I am duly authorised to bring this application on behalf of MSFSA, as is clear from a copy of the resolution attached as annexure **"CS1"**.

4 I have read the founding affidavit in this interlocutory application deposed to by Mr Anele Yawa, the General Secretary of the Treatment Action Campaign NPC ("TAC"). I confirm the correctness of Mr Yawa's affidavit insofar as it refers to MSFSA and me.

5 Except where otherwise stated or indicated by the context, the facts contained in this affidavit are within my personal knowledge, and are, to the best of my knowledge and belief, both true and correct. Where I make legal submissions, I do so on the advice of TAC's and MSFSA's legal representatives, which advice I believe to be correct.

INTRODUCTION

6 In addition to acting as a confirmatory affidavit in respect of certain evidence contained in the founding affidavit in this interlocutory application, the purpose of this affidavit is two-fold:

6.1 First, to explain MSFSA's interest in the main application; and

6.2 Second, to set out the additional evidence that MSFSA seeks to introduce to the record, the relevance of such evidence to the main application, how it differs (or is likely to differ) from that of the parties to the main application, and how it will be of assistance to this Court.

7 In what follows below, I deal with each of these two sets of issues in turn.

MSFSA'S INTEREST IN THE MAIN APPLICATION

8 MSFSA's interest in the main application flows from its experience in advocating for access to medicines, both domestically and internationally, through the Access Campaign. Part of MSFSA's parent body, Médecins Sans Frontières ("MSF"), the Access Campaign is comprised of a relatively large team from across the world, that includes experts in medicine, pharmacology, law, and policy, working in various locations. As already indicated, I am based at the MSFSA head office in Johannesburg.

9 The Access Campaign's website (https://www.msfaccess.org) explains:

> *"The Access Campaign is part of Médecins Sans Frontières (MSF), an international, independent, medical humanitarian organisation.*
>
> *Our work is rooted in MSF's medical operations and supports people in our projects and beyond.*
>
> *We bring down barriers that keep people from getting the treatment they need to stay alive and healthy. We advocate for effective drugs, tests and vaccines that are:*
>
> - *available,*
> - *affordable,*
> - *suited to the people we care for, and*
> - *adapted to the places where they live."*

10 The Access Campaign was launched in 1999, at a critical time for global health. From the mid-1990s, wealthier countries had been able to provide treatment to persons living with HIV by giving them access to new and effective drugs called antiretrovirals.

11 However, access to these drugs was simply not forthcoming for most people in developing countries like South Africa. This differential in access was, in large part, as a result of the excessively high prices being charged by pharmaceutical companies, enabled by patent protection. This kept the medicines out of reach for most of those living with HIV in countries such as South Africa.

12 When the Access Campaign began, its aim was to improve access to antiretroviral treatment ("ART"). To that end, when MSF started operating in

South Africa, it began by providing ART to people living with HIV in the Cape Town township of Khayelitsha. (MSFSA, as a separate juristic entity, was only established in 2007.)

13 In its work in the field, MSF was developing an increasing sense of frustration at the fact that medicines and diagnostics were either priced out of reach, or were not useful or effective when used in the field. The Access Campaign was set up as a response, seeking to access these essential tools by overcoming policy, law, and other systemic barriers.

14 In its advocacy work, MSF partnered with civil society organisations (such as TAC) and community-based health activists (such as TAC members) to raise awareness of the need to ensure access to lifesaving medicines for patients with HIV, including antiretrovirals and other medicines.

15 The aim of the Access Campaign has since expanded beyond access to ART. It now also seeks to promote access to medicines more broadly, with projects and works that include a focus on access to medicines, vaccines, and diagnostics for other diseases. These include TB, malaria, hepatitis C, tropical and neglected diseases (such as Ebola and snakebite), COVID-19, and diabetes. In particular, the Access Campaign aims to eliminate barriers that prevent people from accessing the treatment they need to stay alive and remain healthy.

16 To do so, the Access Campaign advocates for effective medicines, tests, and vaccines that are available, affordable, suitable to the people for whom MSF cares, and are appropriately adapted for the places where the users live.

17 One of the key components of the Access Campaign in South Africa is the work on domestic legal and policy reform to facilitate access to medicines, including work to remove barriers to access in respect of specific medical products. In this work, there is a focus on, among other things, the lack of access to medicines due to their high cost, in large part a result of the country's patent legislation, and how it is implemented.

18 In the circumstances, we submit that the work we have done (and continue to do) on access to medicines, both domestically and internationally, provides sufficient basis for this Court to recognise MSFSA's interest to be admitted as *amicus curiae* in the main application.

MSFSA'S ADDITIONAL EVIDENCE

19 Many of the victories that were won in the advocacy and litigation on access to medicines centred on the HIV/AIDS pandemic, which has seen unprecedented levels of illness and loss of life. All of these victories were won through *ad hoc* pursuits that, in the South African context, did not involve any reform of the patent system. What this means is that certain barriers in the system that inhibit access to medicines remain.

20 In our experience working in South Africa, the often excessively high prices of patented medicines affect both the public and private sectors.

20.1 In the private sector, medicines under patent are often not fully covered by medical schemes, whose obligations to cover the full costs of prescribed minimum benefits ordinarily do not extend to such medicines.

20.2 In the public sector, the high cost of patented medicines often means that they are either not provided at all, or only provided in limited and/or exceptional circumstances.

21 Where the state and/or medical schemes are unable to cover the high costs of medicines, it is often impossible – or extremely difficult – for individual patients to cover treatment costs out of pocket. The result is that the lack of access to lifesaving or other medicines ordinarily results in patients' premature death, or significantly reduce their quality of life.

22 When medicines under patent are inaccessible, whether due to high prices, supply constraints and/or any other challenges, states and third parties (such as pharmaceutical companies that manufacture generic medicines) should be able to invoke the array of flexibilities recognised by the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") to increase access. One such flexibility is compulsory licensing.

23 But despite there having been numerous instances that would have justified the grant of such licences in South Africa, to date, not a single one has been granted. We do not intend to speculate as to why a provision such as section 56 of the Patents Act 57 of 1978, which makes provision for the grant of compulsory licences in certain circumstances, has never been used in South Africa. Instead, we wish to set out some of the barriers to access to three specific medicines that we have studied, which – under TRIPS – ought to have been addressed.

Access to medicines to treat tuberculosis ("TB")

24 In September 2016, as part of the Fix the Patent Laws ("FTPL") campaign, we published a report titled *"Patent barriers to medicine access in South Africa: A case for patent reform"*. Copies of relevant excerpts from the report are attached collectively as annexure **"CS2"**. In what follows immediately below, I set out some of the findings that we made on access to TB medicines.

25 South Africa has one of the highest burdens of TB and drug-resistant TB. And TB is one of our leading causes of death. For the first time in over 50 years, new drugs are becoming available to treat drug-resistant TB. But the treatment regimen for drug-resistant TB involves the administration of multiple drugs. And the newer drugs are under patent protection.

26 To treat drug-resistant TB effectively, these new drugs must be made available to as many patients as possible as options in their treatment regimens. But the individual and combined cost of these new drugs is a major barrier to their

accessibility. In our work through the FTPL campaign, we have focused on three medicines for drug-resistant TB that have (or had) limited accessibility.

27 The first drug is linezolid, which is marketed in South Africa by Pfizer Laboratories (Pty) Ltd as Xyvoxid. In 2012, while still under patent, the drug was offered to the public sector for R282 (for a single 600 mg tablet), and was sold for R593 per tablet to the private sector. In this regard, I attach – as annexure **"CS3"** – a copy of a factsheet published by the FTPL campaign in 2012 titled *"Highlighting medicines affected by strict IP laws: Linezolid"*.

28 At that time, the cost of a generic version of the medicine in India, where Pfizer did not have any patent protection, was only R13 per tablet: that's 4.6% of the price of the medicine offered to the South African public sector, and just 2% of the private sector price.

29 The high cost of the drug in South Africa meant that most patients here could not afford to pay for it out of pocket. And its high cost meant that it was not procured for use in the public sector. The drug only became available in the public sector in March 2016, some 19 months after patent expiry (in August 2014).

30 The second drug is bedaquiline, brought to the market by the Johnson & Johnson company Janssen Pharmaceutica NV. According to patent database MedsPaL (https://www.medspal.org), run by the Medicines Patent Pool ("MPP"), the original compound patent is due to expire on 18 July 2023, with the patent for use to treat multi-drug resistant TB (on its own and/or in combination with other

antimycobacterial agents) only expiring on 24 May 2025. Other secondary patents expire even later, up to 2027.

31 In 2016, the lowest price Janssen had announced for the six-month treatment course of bedaquiline in any country was R12,726, or about R70/day. By October 2019, the price for bedaquiline was still too high. As a result, we launched a global campaign calling on Janssen to lower its price to no more than 1 USD per day for people who need it.

32 The reason for our demand was to facilitate an upscale in the treatment of drug-resistant TB, and to reduce deaths. A key basis for our demand was that the drug had been developed using a considerable amount of taxpayer, non-profit, and philanthropic funding. A copy of the media statement for the campaign launch is attached as annexure **"CS4"**. It provides further detail:

> *"Much of the critical work to inform the use of the drug and demonstrate its therapeutic value was conducted by the TB research community, health ministries, and treatment providers including MSF, and was financed by taxpayers and other donors.*
>
> *Despite this joint research and development effort by the global TB community, J&J alone owns the patent on the drug in many countries and has sole rights to determine in which countries the drug will be sold. Moreover, J&J also benefited from a significant financial windfall as it obtained a Priority Review Voucher from the US Food and Drug Administration (USFDA), that can be used to get accelerated marketing approval for another of its drugs."*

33 Part of our work on bedaquiline has included a focus on the production and supply of generic alternatives. In a press statement dated 16 January 2023, a

copy of which is attached as annexure **"CS5"**, the Access Campaign explained the basis upon which it was supporting a challenge to a secondary patent application in India:

> *"Since 2020, bedaquiline has become the backbone for all DR-TB regimens recommended by the World Health Organization (WHO). However, it currently accounts for 35-70% of the overall cost of most of the drug-resistant TB (DR-TB) treatment regimens. With treatment scale-up and competition among generic manufacturers to begin by July 2023, the price of bedaquiline could soon come down by as much as 80%, i.e., from the current lowest price of US$45 per person per month to as low as $8-17 per person per month.*
>
> *Several Indian manufacturers are ready to supply the generic version of this lifesaving drug upon the expiry of the basic patent in July 2023. Generic manufacturers have already applied to the WHO's 'Pre-Qualification' programme, which assures quality of products for low- and middle-income countries and treatment providers."*

34 On 23 March 2023, MSF announced that the challenge had been successful, with the Indian Patent Office having rejected Johnson & Johnson's attempt *"to extend its monopoly in India on the TB drug bedaquiline beyond the primary patent's expiry this July."* A copy of the press release is attached as annexure **"CS6"**. It remains to be seen what impact, if any, this will have on access in South Africa, where bedaquiline will remain under patent.

35 The third drug is delamanid, which is manufactured by Otsuka Pharmaceutical Co., Ltd. Prior to March 2019, the drug was patented in South Africa and had not been registered with the South Africa Health Products Regulatory Authority ("SAHPRA"). As a result, there was limited access to the drug as –

35.1 patients had to apply for special authorisation in terms of section 21 of the Medicines and Related Substances Act 101 of 1965; and

35.2 the lowest price Otsuka had offered (since September 2019) for a six-month treatment course of delamanid, in South Africa, remained at a shockingly high R19,726 (or just under R110/day).

36 In or about March 2019, delamanid was registered with SAHPRA. But that, on its own, was not enough. According to the MPP's MedsPaL, the original compound patent is only due to expire on 10 October 2023, with the patent for use in combination with other TB drugs only expiring on 4 October 2026.

37 As a result of secondary patents on bedaquiline and delamanid, access to affordable generic products in South Africa will remain a far-off dream, long after the expiry of the compound patents later this year. While bedaquiline is currently provided in the public sector, the high cost of the medicine limits the number of people who are able to benefit.

38 In a study presented as far back as October 2015, researchers found that the target prices for drugs such as bedaquiline and delamanid were more than 90% lower than the going price for these drugs. In an article published by the UK-based charity NAM on https://www.aidsmap.com, Keith Alcorn explained:

> *"The cost of newer drugs for the treatment of multidrug-resistant tuberculosis (MDR-TB) could be cut by up to 95% if generic production of patented products could be achieved in the same way as for antiretroviral drugs, according to a study presented at the 15th European AIDS Conference in Barcelona on*

> *Thursday. Price reductions might permit a tenfold increase in the number of people who can be treated for MDR-TB within current budgets, without any new funding, the study suggests.*
>
> *The cost of drugs to treat MDR-TB often run into thousands of dollars, limiting how many people can be treated and leading to further spread of MDR-TB in settings where resources are limited."*

39 A copy of the article is attached as annexure **"CS7"**.

Access to medicines for hepatitis C

40 Hepatitis C is a liver infection caused by the hepatitis C virus ("HCV"). Principally through cirrhosis, liver failure, and liver cancer, hepatitis C kills more than 400,000 people worldwide each year, mainly in developing countries. Yet the disease is both treatable and curable.

41 In December 2013, the US Food and Drug Administration approved the use of sofosbuvir *"for the treatment of chronic hepatitis C … infection as a component of a combination antiviral treatment regimen."* It revolutionised the treatment of hepatitis C. In comparison to what was available at the time, sofosbuvir required a much shorter course of treatment (12 weeks as opposed to 24 – 48 weeks), and was far more effective at curing hepatitis C (>95% effectiveness vs <50%).

42 The drug was brought to the market by Gilead Sciences, Inc., which sold it in the US and other developed countries for US$1,000/pill, or US$84,000 for the 12-week course. This cost has meant that middle to high-income countries ration the drug by providing it only to those who are at the most advanced stage of the

disease. At the current exchange rate of ±R18 to the dollar, a single treatment course – at this price – would cost over R1.5 million.

43 The pricing of sofosbuvir brought to the fore the disparity between the cost of producing a drug and its sale price. In a study published in the *Journal of Virus Eradication* in 2016, titled "Rapid reductions in prices for generic sofosbuvir and daclatasvir", Andrew Hill et al found that it was possible to produce generic versions of sofosbuvir at a fraction of the price. In the study, a copy of which is attached as annexure **"CS8"**, the authors explained:

> *"Sofosbuvir with daclatasvir, currently the most effective pan-genotypic combination treatment, could be sustainably produced at a price of US$200. The price for the requisite laboratory tests for diagnosis and treatment monitoring, if using a pan- genotypically effective regimen like sofosbuvir–daclatasvir, has been reported as US$56 per patient. By combining this estimate of testing costs with our present cost-based price estimates, [w]e propose that testing, treatment and monitoring is currently possible at US$256 per patient, for a 12-week sofosbuvir–daclatasvir regimen, with no genotyping. At current trends, these per-patient costs could show progressive reductions below this price in the next 2–3 years."* (Footnotes omitted)

44 In a press release dated 31 October 2017, MSF recorded that it had *"secured deals for generic hepatitis C medicines for as low as US$1.40 per day, or $120 per 12-week treatment course for the key medicines sofosbuvir and daclatasvir."* At that stage, MSF had been procuring sofosbuvir and daclatasvir through the patent holders' "access programmes" – at US$1,400 to US$1,800 per 12-week treatment. A copy of the press release is attached as annexure **"CS9"**.

45 In an article titled “The Power of TRIPS Flexibilities in Medicines Procurement”, Dr Ellen 't Hoen – a former director of policy at the Access Campaign, and the first executive director of the MPP – explained how Malaysia was able to take advantage of the deal and begin rolling out treatment for people with hepatitis C. Malaysia is a country with a high burden of the disease. It is also a country in which sofosbuvir is patented, with the compound patent only expiring in 2028.

46 In her article, a copy of which is attached as annexure **“CS10”**, 't Hoen explained:

> *“Treatment will be a combination of antivirals (sofosbuvir and daclatasvir) from generic producers, including the Egyptian company Pharco, which has offered the curative 12 week HCV treatment for US$ 120. Egyptian companies are able to make generic HCV medicines because relevant patents on sofosbuvir and daclatasvir do not exist in Egypt. (For information about patent status of HCV medicines visit www.medspal.org)*
>
> *Malaysia, however, had granted patents on sofosbuvir. To enable purchase of low cost generic antivirals, on 20 September 2017 Malaysia issued a compulsory licence for sofosbuvir. As a result, the price of treatment has dropped from RM 50000 (US$ 13,000) to RM 1000 (US$ 258) and is expected to drop further to RM 500 (US$ 129)[.] The decision to issue a compulsory licence to enable the purchase of low-priced generic products was central to the Malaysian government’s HCV treatment plan. … An estimated 400,000 people infected with HCV live in Malaysia.”*

47 In a press release dated 20 September 2017, Malaysia’s Minister of Health explained the basis for his country’s decision:

> *“As Hepatitis C has become a major public health concern in Malaysia, it is crucial to increase access to its treatment for the benefit of the nation. Therefore, the Cabinet has approved the use of Rights of Government under Patent Act 1983 (Act 291) by exploiting the patented invention of Sofosbuvir*

> *tablet 400mg. The last time Malaysia instigated the Rights of Government was in 2003 for anti-retroviral drugs (treatment for HIV infection). This sets Malaysia to be the first country to initiate such move in the world."*

48 A copy of the press release is attached as annexure **"CS11"**.

Access to vaccines and treatment for COVID-19

49 The response to the COVID-19 pandemic serves as a recent and stark example of how intellectual property rights, and patents in particular, may undermine an effective global solution to a global problem. In addition to global mechanisms, we need to strengthen and reform national mechanisms to deal with inequities at the individual country level.

50 In the founding affidavit, Mr Yawa deals with the Ministerial Decision on the TRIPS Agreement, which was adopted by the World Trade Organization ("WTO") on 17 June 2022. In what follows below, I focus on a joint technical brief on access to vaccines and treatment for COVID-19 that the Access Campaign prepared in collaboration with the People's Health Movement (South Africa), prior to the WTO's final decision. A copy of the brief is attached as annexure **"CS12"**.

51 Titled "Removing intellectual-property barriers from COVID-19 vaccines and treatments for people in South Africa", the brief considers the barriers in the way of accessing Moderna's mRNA vaccine (which has not been used locally), and various treatment drugs. These include medicines such as baricitinib, which has

previously been approved for treating rheumatoid arthritis, and nirmatrelvir, an oral antiviral treatment used in combination with the antiretroviral ritonavir.

52 Of particular concern to us in preparing the brief was the issue of supply. What the COVID-19 pandemic has demonstrated clearly is that the issue of cost, while central to any debate on access, is not the only issue to address. Rather, as appears to be the case in the main application, sustainability of supply must also be assured. As the brief explains:

> *"South Africa has existing generic production capacity that could produce medicines such as baricitinib and nirmatrelvir/ritonavir. Given the present and emerging patent barriers and the limitations of voluntary licenses as mentioned above, removing any IP barriers and uncertainties is important to facilitate local production and diversified supply of generic COVID- 19 therapeutics, to help ensure uninterrupted and more affordable access."*

53 While the brief focuses on patent law reform, it also recognises that – while imperfect – the Patents Act already makes provision for the grant of compulsory licences, and should indeed be used for this purpose. While there may be some debate on the manner in and extent to which section 56 ought to be interpreted (in line with the Constitution), the facts of the main application make it clear that if ever there was a justification for using the provision, this is it.

CONCLUSION

54 Accordingly, I pray for the relief as set out in the notice of motion.

_____
ANDISIWE CANDICE SEHOMA

I hereby certify that the deponent has acknowledged that she knows and understands the contents of this affidavit, and that it is to the best of her knowledge both true and correct. This affidavit was signed and sworn to before me at _____ on this the ____ day of April 2023.

_____
COMMISSIONER OF OATHS