**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 –

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

*In re*: the matter between –

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

and

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| **VERTEX PHARMACEUTICALS INC.** | Respondent |

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**FOUNDING AFFIDAVIT**

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I, the undersigned,

**ANELE YAWA**

do hereby state the following under oath:

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1 I am the General Secretary of the Treatment Action Campaign NPC ("TAC"), a non-profit organisation with its national office located on the 10th floor of Nedbank House, 85 Main Street, Marshalltown, Johannesburg. TAC is registered as a non-profit company (registration no. 2000/029181/08). I am also a director of TAC, and – in my capacity as General Secretary – a member of its National Council.

2 I am duly authorised to bring this application on behalf of TAC, as is clear from a copy of the resolution attached as annexure **"AY1"**. I have been advised that Ms Candice Sehoma is authorised to bring this application on behalf of Médecins Sans Frontières Southern Africa NPC ("MSFSA"), and will depose to an affidavit in support of the application. Ms Sehoma is MSFSA's Advocacy Advisor.

3 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**

4 In this application, brought in terms of rule 16A(5) of the Uniform Rules of Court, TAC and MSFSA seek to be admitted as *amici curiae* ("*amici*") in the application for a compulsory licence brought by Cheri Nel and the Cystic Fibrosis Foundation (Central Region) against Vertex Pharmaceuticals Inc. ("the main application").

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5 Having considered the founding papers in the main application, TAC and MSFSA submit that they are well-placed to put evidence before this Court, and to make both written and oral submissions, that will assist it in its determination of the matter. They further submit that their evidence and submissions will be relevant to the proceedings, and different from those of the parties to the main application.

6 The need for this application flows from the effective refusal of the respondent in the main application, Vertex Pharmaceuticals Inc. ("Vertex"), to consent to TAC and MSFSA being admitted as *amici*. (The applicants have granted consent.) In light of the role *amici* ordinarily play in our legal system, by drawing the attention of courts *"to relevant matters of law and fact to which attention would not otherwise be drawn"*, I submit that this effective refusal is unreasonable. I deal further below with the basis upon which Vertex withheld its consent.

7 In what follows in this affidavit, I consider the following issues in turn:

7.1 First, TAC's interest in the main application;

7.2 Second, the attempts made by TAC and MSFSA to secure the parties' consent for the two organisations to be admitted as *amici*;

7.3 Third, the additional evidence that TAC seeks to introduce to the record, the relevance of such evidence to the main application, how it differs (or

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is likely to differ) from that of the parties to the main application, and how it will be of assistance to this Court;

7.4 Fourth, a summary of the legal submissions that TAC and MSFSA intend to make if admitted as *amici*, the relevance of such submissions to the main application, how they are likely to differ from those of the parties to the main application, and how they will be of assistance to this Court; and

7.5 Finally, the basis upon which TAC and MSFSA seek condonation for the late filing of this application.

8 I have been advised that the supporting affidavit to be deposed to by Ms Sehoma will, in addition to acting as a confirmatory affidavit, deal with –

8.1 MSFSA's interest in the main application; and

8.2 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 those of the parties to the main application, and how it will be of assistance to this Court.

**TAC'S INTEREST IN THE MAIN APPLICATION**

9 TAC is a membership-based activist organisation that seeks to ensure the realisation of the right to have access to health care services across South Africa.

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Its vision contemplates a health care system that provides quality services to all, regardless of who they are, where they live, and what they are able to pay. In accordance with its Constitution, a copy of which is attached as annexure **"AY2"**, TAC campaigns for access to medicines of proven quality, safety, and efficacy.

10 TAC has over 8,000 members, a network of 229 branches across South Africa, in eight of the country's nine provinces. Since its inception, TAC has had a special focus on persons living with and affected by HIV, and on the provision of comprehensive prevention and treatment services for HIV and TB. Part of this focus has seen TAC engaging in various forms of monitoring and advocacy, undertaking campaigns aimed primarily at ensuring the provision of quality comprehensive care in the public sector, and targeted legal action.

11 From its launch in December 1998, when it began to campaign for access to antiretroviral ("ARV") treatment, TAC has grown into – and continues to be – one of the world's most formidable and impactful civil society organisations working in the field of HIV. Its campaign for access to ARV treatment focused not only on the state as the primary provider of health care services for people living with HIV, but also on eliminating various barriers – including the excessively high prices of ARV and other medicines – that stood in the way of people with HIV accessing appropriate treatment, whether in the public or private sector.

12 To achieve its objectives, TAC employs a combination of strategies, including legal action. In its litigation, TAC has always sought to secure systemic relief. Since its birth almost 25 years ago, TAC has been both applicant and *amicus* in

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numerous superior court matters. Among others, TAC has been involved in the following reported cases (listed in descending chronological order):

12.1 *Nkala and Others v Harmony Gold Mining Co Ltd and Others* (2016 (5) SA 240 (GJ)), a case dealing with the certification of a class action for damages in the context of occupationally-acquired silicosis (as *amicus*);

12.2 *Lee v Minister of Correctional Services* (2013 (2) SA 144 (CC)), a case dealing with the respondent's liability for the damages suffered by the applicant as a result of contracting TB while in detention (as *amicus*);

12.3 *Treatment Action Campaign v Minister of Correctional Services and Another* ([2009] ZAGPHC 10), a case dealing with access to a report of the then Judicial Inspector of Prisons regarding an investigation into the death an inmate with HIV at a correctional centre (as applicant);

12.4 *N and Others v Government of the Republic of South Africa and Others (No 1)* (2006 (6) SA 543 (D)), a case dealing with the constitutional obligations of the state to provide access to health care services for inmates (as applicant);

12.5 *Cipla Medpro (Pty) Ltd v Aventis Pharma SA; Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others* (2013 (4) SA 579 (SCA)), a case dealing – in part – with the impact of public interest

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considerations on the balance of convenience test in applications for interim interdicts (as *amicus*);

12.6 *Treatment Action Campaign and Another v Rath and Others* ([2008] 4 All SA 360 (C)), a case dealing – in large part – with the legal obligations of the then Medicines Control Council (now the South African Health Products Regulatory Authority) to protect the public (as applicant);

12.7 *Treatment Action Campaign v Rath and Others* 2007 (4) SA 563 (C), a case in which an interim interdict was sought – and obtained – to restrain the respondents from continuing to publish defamatory statements that alleged an improper and unethical relationship between TAC and the pharmaceutical industry (as applicant);

12.8 *Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others* 2006 (2) SA 311 (CC), a case challenging the lawfulness of pricing regulations targeting various aspects of the medicines supply chain (as *amicus*); and

12.9 *Minister of Health and Others v Treatment Action Campaign and Others* 2002 (5) SA 721 (CC), a case dealing with the state's obligations to provide services aimed at preventing the transmission of HIV during pregnancy and/or labour, and following childbirth (as applicant).

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13 TAC was also involved in two other matters, which both settled, in which access to medicines was core: one as *amicus*, and another as a complainant (before the Competition Commission of South Africa ("the Commission")). While the first case considered access to medicines broadly, the second focused solely on access to three ARV medicines.

13.1 The first case concerned a challenge brought by the then Pharmaceutical Manufacturers' Association of South Africa ("PMA") and 39 others to the Medicines and Related Substances Control Amendment Act 90 of 1997. As a result of delays on the part of the applicants and respondents, that matter – under case number 4183/98 (TPD) – took almost three years to get to court. But within six weeks of TAC having been admitted as *amicus*, the matter was settled, resulting in the withdrawal of the case. It would, however, take a number of years for the law to come into force.

13.2 The second case concerned an excessive pricing complaint lodged with the Commission by ten individuals and organisations, including people living with HIV, health care providers, a trade union federation, a trade union, TAC, and another not-profit organisation working in the field of HIV. Within two months of the matter being referred to the Competition Tribunal for adjudication, the complainants entered into settled agreements with the respondents which resulted in generic versions of the ARV medicines in question entering the local market. (I deal with this case further below.)

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14 TAC's work on access to medicines has included a particular focus on the role played by the patent system in limiting access to medicines. Alongside MSFSA, TAC was a founder member of the Fix the Patent Laws ("FTPL") Campaign, a coalition of more than 40 organisations that advocate for the reform of the Patents Act 57 of 1978 ("the Patents Act"), to bring it in line with the constitutional promise of access to health care services, and to take full advantage of the public health safeguards and flexibilities recognised in international law, including provisions on government use authorisations and compulsory licensing.

15 I submit that TAC has demonstrated its clear interest in the subject matter of the main application, which – among other things – concerns the proper interpretation (and application) of section 56 of the Patents Act, so as to *"promote the spirit, purport and objects of the Bill of Rights"*, which includes a right to have access to medicines as an integral part of the right in section 27 of the Constitution to have access to health care services. While TAC is of the view that the Patents Act is currently unconstitutional, it nevertheless submits that it can and ought to be interpreted to grant the relief sought by the applicants in the main application.

**ATTEMPTS TO SECURE THE PARTIES' CONSENT**

16 Acting on behalf of TAC and MSFSA, SECTION27 sent a letter to the attorneys of all parties in the main application, requesting consent for its clients to be admitted as *amici*. In that letter dated 1 March 2023, a copy of which is attached as annexure **"AY3"**, the parties were requested to respond by 15 March 2023.

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Both the applicants' and respondent's legal representatives responded timeously to the letter seeking consent.

17 SECTION27 's letter ran to four pages. It started with a brief description of TAC and MSFSA, followed by a summary of their interests in the main application. It then dealt with two issues: first, the legal submissions that TAC and MSFSA intend to make, if admitted as *amici*; and second, the proposed evidence that both organisations seek to adduce: to place their legal submissions in their relevant context, and *"to allow the Court to understand the broader ramifications of the relief sought by the applicants [in the main application]"*.

18 On 9 March 2023, Mr Tim Ball of Webber Wentzel, the attorneys representing the applicants in the main application, addressed an email to our attorneys to which two documents were attached: first, a copy of the rule 16A notice that the applicants had recently filed; and second, a letter confirming that they *"have no objection to Médecins Sans Frontières Southern Africa NPC and the Treatment Action Campaign NPC intervening as amici curiae in the matter."* Copies of the documents are attached as annexures **"AY4"** and **"AY5"** respectively.

19 On 10 March 2023, Mr Alexis Apostolidis of Adams & Adams, the attorneys representing the respondent in the main application, addressed a letter to our attorneys advising them that Vertex *"has no objection, in principle, to MSFSA and TAC being admitted as amici … and would welcome their contribution to any of the issues that are relevant to Ms Nel's case."* A copy of the letter is attached as annexure **"AY6"**.

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20 In that letter, however, Mr Apostolidis also stated that Vertex *"is concerned that [the] proposed intervention, as set out in [SECTION27's] letter, may broaden the scope of the issues beyond those that are relevant to the determination of Ms Nel's case."* Accordingly, he made clear, Vertex was *"not in a position to decide now whether to consent or oppose the admission of MSFSA and the TAC."*

> *"It will be in a position to do so once it has had an opportunity to consider your full application for admission as amici curiae and, in particular, what evidence you propose to introduce into the proceedings."*

21 TAC and MSFSA were therefore asked to file this application so that Vertex *"may consider its position and respond in due course."* I am advised that a more appropriate response may have been to seek further clarity on the nature and extent of the proposed intervention. That said, we trust that Vertex will see fit not to oppose TAC's and MSFSA's application to be admitted as *amici* once it has had an opportunity to consider the founding papers.

**EVIDENCE THAT TAC SEEKS TO ADDUCE**

22 The nature and extent of the evidence sought to be adduced by TAC and MSFSA was identified in SECTION27's letter seeking the parties' consent:

> *"11. In order to place their legal submissions in their relevant context, and to allow the Court to understand the broader ramifications of the relief sought by the applicants, our clients wish to place on record their practical experiences in campaigning for and facilitating access to medicines, and to document relevant domestic and international developments. Our*

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*clients are of the view that knowledge of these historical events will ensure that the Court is well-placed to understand the key role that section 56 of the Patents Act may play in unlocking access to medicines, and what this may mean for its proper interpretation and application.*

12. *In addition, our clients wish to place evidence before the Court on why the socio-economic landscape of South Africa demands that all medicines be made affordable, regardless of the sector in which they are used. Because the founding papers focus primarily on the private health sector, our clients' evidence will seek to provide insight into access to medicines in the public health sector. In particular, this aspect of our clients' evidence will demonstrate how the two health sectors are interconnected, and what limiting access to medicines in the one may do to the other."*

23 On further reflection, TAC has decided against placing evidence before this Court dealing with South Africa's socio-economic landscape, and why it demands that all medicines be made affordable, regardless of the health sector in which they are sold and/or used, and how the public or private sectors are interconnected. Instead, we will seek this Court's permission to make limited legal submissions on this issue by including a focus on the right to equality.

24 In what follows below, I deal with the following four issues in turn:

24.1 First, a consideration of some of the domestic campaigns that TAC ran to increase access to various medicines, and why the campaigns – although successful – highlight the need for broader systemic reform;

24.2 Second, relevant international developments that have sought to address barriers to access posed by patent protection;

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24.3 Third, policy and law reform efforts in South Africa aimed at addressing these types of barriers; and

24.4 Finally, the relevance of this new evidence to the main application, how it differs (or is likely to differ) from the evidence of the parties to the main application, and how it will be of assistance to this Court.

**TAC's domestic campaigns for access to medicines**

25 Our work on access to medicines has taken various different forms, including assessing the affordability of key medicines, developing drug and/or disease-specific advocacy campaigns, engaging in policy and law reform processes, and using litigation (as inadequate as the law currently may be). In what follows, I consider two examples of TAC's access to medicines work. They both make it clear that our work, as important as it may be, is no substitute for a comprehensive legislative framework, and direct state action.

<u>The Christopher Moraka Defiance Campaign</u>

26 One of the first multinational companies to incur TAC's opprobrium was Pfizer, which marketed the patented antifungal drug Diflucan – containing the active ingredient fluconazole – at what TAC believed to be an excessively high price. Fluconazole is used to treat a number of opportunistic infections in people living with HIV. It was of particular importance at a time in South Africa when very few

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people with HIV had access to ARV treatment, resulting directly in many painful and preventable deaths.

27 In 2000, a single 200mg capsule of Diflucan was sold to the public sector for R28.57, with the same medicine being sold into the private sector at R80.24. In Thailand, a quality generic version – marketed as Biozole – sold for the equivalent of just R1.78 a pill.

28 In response, TAC launched what we later called the Christopher Moraka Defiance Campaign, in honour of one of our volunteers who could not access fluconazole, and later died of cryptococcal meningitis. As a key part of the campaign, *"TAC challenged Pfizer to lower its price for fluconazole to R4.00 per 200mg capsule"*. But instead of reducing its price, Pfizer put a donation programme in place.

29 TAC's response is set out in a press release dated 17 October 2000, a copy of which is attached as annexure **"AY7"**. In that response, TAC explained:

> *"In March 2000, TAC challenged Pfizer to lower its price for fluconazole to R4.00 per 200mg capsule (still double the generic price). After TAC's campaign started, Pfizer had announced a donation of fluconazole for cryptococcal meningitis free for all people with HIV/AIDS who could not afford the drug. Pfizer has made its donation a public relations exercise to disguise profiteering. Daily people are still dying because of conditions that are treatable and preventable with fluconazole yet, Pfizer has not yet finalized its agreement with the Ministry of Health, neither has it met the Health Minister's request for a lower price. On 13 July 2000, TAC announced its Defiance Campaign Against Patent Abuse and AIDS Profiteering at the International AIDS Conference in Durban."*

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30 While Pfizer refused to lower the price of Diflucan, TAC's campaign did result in significant improvements to the donation programme: officially called the Diflucan Partnership Program. But even with such improvements, it was never going to be a comprehensive solution to the problem of access to fluconazole in both public and private sectors. Today, years after the expiry of Pfizer's patent, a wide range of generic fluconazole products are available on the South African market.

Making use of the competition law framework and authorities

31 In September 2002, Hazel Tau and ten other complainants, including TAC, approached the Commission for assistance. In their statement of claim, the complainants characterised their complaint as follows:

> *"17. The complainants allege that the companies that are the subject of this complaint have engaged in excessive pricing of ARVs to the detriment of consumers, as prohibited by section 8(a) of the Competition Act, 89 of 1998 (the Act). The excessive pricing of ARVs is directly responsible for premature, predictable and avoidable deaths of people living with HIV/AIDS, including both children and adults. The ARVs in respect of which excessive pricing is alleged are as follows:*
>
> *17.1 AZT (branded as Retrovir®);*
> *17.2 Lamivudine (branded as 3TC®);*
> *17.3 AZT/lamivudine (branded as Combivir®); and*
> *17.4 Nevirapine (branded as Viramune®)."*

32 As noted in paragraph 13.2 above, the complainants later entered into settlement agreements with the respondents which resulted in generic versions of the four ARV medicines entering the local market. The downside of the settlement was

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that the nature of the relationship between intellectual property and competition law was not considered by the Competition Tribunal. To this day, that relationship remains somewhat untested.

33 Mindful that an excessive pricing complaint (against Roche Holding AG) was referred to the Tribunal in February 2022, the Competition Commissioner noted in a recent opinion piece published on *DispatchLIVE* on 3 December 2022

> *"All three scenarios: the Hazel Tau case — the matter of Covid-19 vaccines; and the commission's case against Roche essentially pose one question — where should we draw the line between the rights conferred on pharmaceutical companies by patent law protection and the right of fair access to life-saving pharmaceutical drugs?*
>
> *The Roche case, which is yet to go to trial, is set to debate this very issue.*
>
> *The benefits and incentives of patent law protection are well recorded and widely accepted. However, at the Competition Commission we believe there are instances where this right must be squarely challenged and weighed up against patient rights to access medicines.*
>
> *The Competition Act 89 of 1998, as amended, provides the legislative tools for us to do so within the judicial system.*
>
> *The Tau case concluded with a settlement agreement that achieved the same outcome we would have wanted to see from a contested trial.*
>
> *The distribution of Covid-19 vaccines became more equitable as time passed due, in part, to global social activism in this regard.*
>
> *However, neither case established a precedent or framework from which future matters questioning the balance between patent protection and free access can be assessed.*

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*It remains to be seen what outcomes emanate from the commission's case against Roche but, certainly, whichever way this matter unfolds, it will mark a significant moment in the shaping of our pharmaceutical regime — in much the same way the Hazel Tau case did just 20 short years ago."*

34 A copy of the opinion piece, titled *"Why Hazel Tau's victory on HIV/Aids medicine pricing still matters today"*, is attached as annexure **"AY8"**.

35 TAC engaged the Commission on two further occasions:

35.1 In 2007, it lodged a complaint in respect of efavirenz (an ARV), alleging that MSD (Pty) Ltd and parent company Merck & Co., Inc. had violated section 8(c) of the Competition Act by refusing to license a sufficient number of companies to market generic versions of the medicine, and by refusing to license anyone to market co-formulated and/or co-packaged generic products containing efavirenz and at least one other ARV.

35.2 In 2009, TAC made a submission to the Commission on the proposed merger between two companies: GlaxoSmithKline ("GSK"), and Aspen Pharmacare. In its submission, TAC raised a concern regarding the potential impact of the merger – if approved – on competition for abacavir (a commonly used ARV in the treatment of infants and children living with HIV). At the time, Aspen alone had been granted an abacavir licence.

36 In both cases, TAC's use of competition law had practical outcomes:

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36.1 By the time the Commission decided not to refer the complaint against MSD and Merck to the Tribunal for adjudication, the companies had made significant concessions. *"On the basis of these significant developments"*, a TAC statement dated 30 August 2008 read, *"the Commission believes that there is no reason to refer the complaint to the Competition Tribunal for adjudication on what is now largely a historical complaint."* A copy of the statement is attached as annexure **"AY9"**.

36.2 In a press statement dated 11 September 2009, TAC recorded that as a condition of the merger's approval, GSK had been required to grant licences, on a non-exclusive basis, to six generic companies (five of which were identified "for the manufacture and/or import of abacavir, on terms and conditions no less favourable than those granted to Aspen.") A copy of the statement is attached as annexure **"AY10"**.

**Relevant international developments**

37 Mindful of TAC's various attempts at addressing barriers to access to medicines within South Africa, I now consider relevant developments at the international level, and how these have influenced a number of other countries in the way they have addressed the issue of compulsory licensing in their domestic legislation. In so doing, I demonstrate what South Africa could – and I suggest – ought to do in amending the Patents Act.

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38 On 1 January 1995, the World Trade Organization ("WTO") came into existence. According to the WTO's website, the organisation's creation *"marked the biggest reform of international trade since the end of the Second World War."* One of these "reforms" was the adoption and coming into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), which places a range of obligations on member states regarding their intellectual property laws.

39 A copy of TRIPS is attached as annexure **"AY11"**. It deals with various forms of intellectual property, including copyright, trademarks, geographical indications, industrial designs, and patents. In dealing with patents, Article 27.1 provides that, subject to certain exceptions, *"patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."*

40 TRIPS sets a floor, not a ceiling. It recognises, in Article 1.1, that *"Members may, but shall not be obliged to, implement in their law more extensive protection than is required"*. Article 1.1 also recognises that *"Members shall be free to determine the appropriate method of implementing the provisions of [TRIPS] within their own legal system and practice."* I am advised that this would include the implementation of TRIPS obligations in a manner that recognises – and gives effect to – a member state's domestic constitutional obligations.

41 At a WTO Ministerial Conference held in Doha, Qatar, in November 2001, only months after the PMA and its co-applicants had abandoned their legal challenge in the High Court to Act 90 of 1997, member states adopted the Declaration on

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the TRIPS Agreement and Public Health ("the Doha Declaration"). In the year that preceded the Ministerial Conference in Doha, the developments in South Africa had been brought to the world's attention, and had spurred protest and advocacy across the globe.

42 These events are described in Mark Heywood's *"Debunking 'Conglomo-Talk': A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation"*, (2001) 5:2 *Law, Democracy & Development* 133, a copy of which is attached as annexure **"AY12"**:

> *"Internationally, the TAC formed alliances with Oxfam, MSF, Action for Southern Africa (ACTSA) in Britain and the Health-GAP coalition in the USA – several of these organisations were already campaigning against the pricing practices and abuse of patents by pharmaceutical companies. These allies were able to mount pressure directly against the companies as well as on the governments of industrialised countries. When the case began on March 5th, demonstrations were held in 30 cities world-wide, including in Brazil, the Philippines, the USA, Britain, Kenya, Thailand, France, Italy, Denmark, Australia, and Germany. By this point over 250 organisations from 35 countries had signed a petition opposing the legal action. The civil society mobilisation, supported by international luminaries such as John Le Carre, left the companies increasingly isolated. After the postponement of the case on March 6th, MSF initiated an international petition which collected 250 000 signatures, and during this time played a crucial part in persuading the European Union and Dutch government to pass resolutions calling for the case to be dropped."* (At page 143)

43 I am advised that TRIPS, as is the case with most legal texts, was open to a range of (often contradictory) interpretations. That is why the WTO's consensus position reflected in the Doha Declaration is so important in the context of access to medicines. For example, while recognising that *"intellectual property protection is*

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*important for the development of new medicines"*, it also notes *"the concerns about its effects on prices."* With this in mind, paragraph 4 states:

> *"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.*
>
> *In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."*

44 Paragraph 5 then identifies some of these flexibilities, including – in paragraph 5(a) – the following reference to compulsory licensing:

> *"Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."* (My emphasis)

45 A second reference to compulsory licensing is contained in paragraph 6:

> *"We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."*

46 Although it took much longer than a year for a "solution" to be found and adopted, paragraph 6 of the Doha Declaration ultimately gave rise to the amendment of TRIPS by way of the adoption of Article 31*bis*. In an explanation published on its website, a copy of which is attached as annexure **"AY13"**, the WTO notes:

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> *"The TRIPS Agreement was amended through the Protocol of 6 December 2005 that entered into force on 23 January 2017. The amendment inserted a new Article 31bis into the Agreement as well as an Annex and Appendix. These provide the legal basis for WTO members to grant special compulsory licences exclusively for the production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities for their patients."*

47 I have been advised that the so-called Paragraph 6 system is not relevant to a determination of this matter, because the generic medicines that the applicants seek to procure are already being lawfully produced in Argentina. I have further been advised that the medicines that are the subject of the main application are not protected by patent in Argentina, resulting in there being no need to grant compulsory licences in that country for their production and export. But what is required is a compulsory licence to be issued in South Africa, for the lawful import of such generic medicines.

48 In the more than 20 years since the adoption of the Doha Declaration, much of the global focus on increasing access to medicines has been on the enactment and/or amendment of intellectual property and/or patent statutes to allow for the appropriate use of public health safeguards and flexibilities such as compulsory licensing. In what follows, I provide a few examples of these developments, relying – in large part – on WIPO Lex, a free service of the World Intellectual Property Organization ("WIPO") that provides *"access to legal information on intellectual property (IP) from around the world"*.

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Botswana rewrites its intellectual property law

49 On 29 March 2010, Botswana enacted a new comprehensive industrial property law that deals – among other things – with patents, utility models, industrial designs, trademarks, and geographical indications. Part II of the new Industrial Property Act, 2010, a copy of which is attached as annexure **"AY14"**, concerns patents. Three of the provisions in that part deal with compulsory licences:

49.1 Section 31: *"Compulsory licences in the public interest or for competition"*;

49.2 Section 32: *"Importation of patented products by Government or third party"*; and

49.3 Section 33: *"Compulsory licences for failure to exploit patent"*.

50 Sections 31 and 32 deal with government-issued licences, with both of them referring to Article 31*bis* of TRIPS. While section 31 empowers the Minister of Trade and Industry to authorise government agencies and/or other persons or bodies *"to exploit [a] patented invention"*, section 32 empowers the minister to license government agencies and/or *"authorised persons"* only to import generic versions of patented products.

51 I am advised that both sections allow for the issuing of a compulsory licence where *"[i]t is in the public interest to do so for purposes of national security,*

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*nutrition, health, development of other vital sectors of the national economy, [or] social service".* In addition:

51.1 a section 31 licence may be issued where *"a court of administrative body has determined that the manner of exploitation of the invention by the patentee is anti-competitive or constitutes an abuse of the patent"*; and

51.2 a section 32 licence may be issued where *"the market for the patented product is not being supplied in sufficient quantities or on reasonable terms in relation to market demand."*

52 In contrast, section 33 deals with High Court applications for compulsory licences made by private parties, in circumstances where *"a market for the patent is not being supplied, or is not being supplied on reasonable terms, in Botswana."* Insofar as it is relevant, section 33 provides:

> *"(1) At any time after the expiration of three years from the date of the grant of a patent or four years from the filing date of the application, whichever occurs later, any person may apply to the High Court for an order to be granted a licence under the patent on the grounds that a market for the patent is not being supplied, or is not being supplied on reasonable terms, in Botswana.*
>
> *(2) Notwithstanding the provisions of subsection (1) an order to issue a compulsory licence shall not be granted if the patentee satisfies the High Court that circumstances exist which justify the non-exploitation or insufficient exploitation of the patent.*
>
> *(3) ...*
>
> *(4) ...* (My emphasis)

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53 I am advised that section 33(2) places an onus on the patentee to satisfy the court that it has a justifiable basis for withholding the patented product from a particular market in Botswana, or supplying the patented product to that particular market on unreasonable terms. In the absence of any such justification, the licence would ordinarily be granted, whether for local production and/or importation.

Malaysia amends its Patents Act

54 Like Botswana, Malaysia makes provision – in the recently-amended Patents Act 1983 – for the grant of compulsory licences, upon application, to private parties. And like Botswana, it too makes provision for its minister responsible for intellectual property to authorise a government agency or a third person to exploit a patented invention. And again, like Botswana, its grounds for granting licences differ, depending on the type of licence:

54.1 In the case of licences granted upon application by private parties, they may be issued in any of the following four circumstances:

54.1.1 *"where there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason"*;

54.1.2 *"where there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they do not meet public demand without any legitimate reason"*;

54.1.3 *"where the products produced in Malaysia under the patent for sale in the domestic market are sold at unreasonably high prices without any legitimate reason"*; and

54.1.4 *"for the purposes of production of a pharmaceutical product in Malaysia and exportation of such pharmaceutical product to an eligible importing country to deal with its public health problem."*

54.2 In the case of government-authorised licences, they may be issued –

54.2.1 *"where there is [a] national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires"*; or

54.2.2 *"where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive"*.

55 A copy of the relevant provisions of the Malaysian statute, prior to their most recent amendment (in 2022), is attached as annexure **"AY15"**. A copy of the relevant provisions of the Patents (Amendment) Act 2022 is attached as annexure **"AY16"**.

56 What is particularly interesting about the Malaysian legislation is that courts are not involved in the decision to grant a licence.

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56.1 In the case of an application for a compulsory licence made by a private party, the decision is made by the Registrar of Patents, defined by the Patents Act as the *"Director General of the Intellectual Property Corporation of Malaysia established under the Intellectual Property Corporation of Malaysia Act 2002"*.

56.2 And in the case of a government-issued licence, the decision is made by the minister responsible for intellectual property. That said, in the case of a licence granted to remedy an anticompetitive practice, the minister may only act where a *"judicial or relevant authority"* has made a determination of anticompetitive conduct.

New Zealand rewrites its Patents Act

57 As is the case in both Botswana and Malaysia, New Zealand's Patents Act 2013 draws a distinction between compulsory and government (Crown) use licences. These provisions form an integral part of a statute whose purposes include the provision of *"an efficient and effective patent system that … promotes innovation and economic growth while providing an appropriate balance between the interests of inventors and patent owners and the interests of society as a whole"*, and compliance with the country's international obligations.

58 Subpart 5 of the Act, which deals with compulsory licences, draws a further distinction: between licences issued for the *"supply of patented inventions*

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*predominantly in New Zealand"*, and licences issued solely for the export of pharmaceutical products. Section 171(4) of the Act defines pharmaceutical product to include *"a medicine or vaccine, an active ingredient of a medicine or vaccine that is necessary for its manufacture, or a diagnostic kit needed for the use of a medicine or vaccine"*.

59 In order to obtain a compulsory licence predominantly for domestic supply, whether for local production and/or importation, an applicant must establish either of two things: that *"a market for the patented invention … is not being supplied in New Zealand"*, or that such a market *"is not being supplied on reasonable terms in New Zealand."* The Act does not define what constitutes reasonable terms; a court would have to determine, in the circumstances, if the supply of the patented invention in question was on reasonable terms.

60 In contrast, a licence may be issued solely for the export of a pharmaceutical product if (a) the importing country (or countries) is eligible to import in terms of the WTO's Paragraph 6 system (in Article 31*bis* of TRIPS); and (b) the product *"is needed to address a serious public health problem … specified in the application (for example, an epidemic, whether actual or imminent, of HIV/AIDS, tuberculosis, malaria, or other disease)"*. As is the case with licences issued for domestic supply, these licences may be issued upon application to court.

61 What is particularly interesting about the Crown use provisions is that they permit *"[a]ny government department, and any person authorised in writing by a government department … [to] exploit any invention for the services of the*

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*Crown"*. No particular grounds need to be met. Moreover, section 180(1) of the Act effectively permits the government to decide, for itself, which *"use for the services of the Crown"* ought to be permitted:

> *"Any use of an invention must, for the purposes of this subpart, be treated as a use for the services of the Crown if the Governor-General, by Order in Council, declares that the use of the invention by a person, or by any class of persons, engaged in a particular industry is necessary or desirable to enable full benefit to be derived by the members of the public in New Zealand of any enterprise or undertaking in which the Crown or any government department has a complete or an almost complete monopoly."*

62 I am advised that this provision would allow for the grant of a licence to a local pharmaceutical company to manufacture and/or import any generic medicine required by New Zealand's publicly-funded health care system, in circumstances where the non-availability of that generic medicine stands in the way of the public deriving the full benefit of publicly-funded health care services.

The Medicines Patent Pool enters the field

63 The Medicines Patent Pool ("MPP") was established in 2010 by the global health agency Unitaid, which was itself founded by the governments of Brazil, Chile, France, Norway, the United Kingdom, Spain, and the Republic of Korea. (Among others, the board of Unitaid is made up of representatives of its founding members, a representative designated by the African Union, and representatives from Japan, the World Health Organization, civil society, and foundations.) Further detail on Unitaid is available at https://unitaid.org/.

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64 According to its website, https://medicinespatentpool.org (on which I rely for this section of this affidavit), MPP was established with this vision: *"that non-exclusive voluntary licensing through a public health agency would enable more people in LMICs to access affordable treatments."* The website explains:

> *"MPP started its work in HIV, where there were access gaps in relation to several new antiretroviral medicines. There needed to be an established mechanism for licensing under public health-oriented terms and conditions that would enable manufacturers to develop quality-assured generic products, and make them available where people could not have accessed them otherwise."*

65 What MPP does is to negotiate a master licensing agreement with a patent holder in respect of an identified medicine in need, and then to sublicence generic manufacturers across the world to produce that medicine, for sale in identified countries, on particular terms and conditions. Once in possession of a sublicence, a generic manufacturer does not have to engage with the patentee; it may simply use the invention in question, subject only to local regulatory requirements.

> *"Negotiating public health-driven licences with patent holders, sublicensing to generic manufacturers and product developers, and supporting access to those treatments in LMICs, are the core work of the Medicines Patent Pool."*

66 Over the past 13 years, *"MPP has signed agreements with 18 patent holders for 14 HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a cancer treatment, four long-acting technologies, three oral antiviral treatments for COVID-19 and 12 COVID-19 technologies."* Given the focus of its work, and the limited disease areas in which it operates, it is highly unlikely that MPP could ever come to the applicants' help.

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The Covid pandemic reignites calls for systemic change

67 Despite what appears at face value to be significant progress by MPP, the Covid pandemic has nevertheless shown that a solution that relies on patentees' goodwill – on its own – is grossly insufficient. Of the 15 master licences secured in the Covid field, 11 concern patents held by the United States National Institutes of Health. None of these could be used to facilitate the market entry of a generic version of any Covid vaccine. The same applies to the remaining four licences, three of which concern privately-held patents.

68 On 2 October 2020, the WTO received a communication from South Africa and India *"request[ing] that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19."* These provisions concern all the obligations imposed on member states in relation to copyright and related rights, industrial designs, patents, and the protection of undisclosed information. A copy of the communication is attached as annexure **"AY17"**.

69 The communication sought to justify the adoption of a TRIPS waiver:

> 5. *An effective response to [the] COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.*

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6. *The outbreak has led to a swift increase in global demand with many countries facing acute shortages, constraining the ability to effectively respond to the outbreak. Shortages of these products has put the lives of health and other essential workers at risk and led to many avoidable deaths. It is also threatening to prolong the COVID-19 pandemic. The longer the current global crisis persist, the greater the socio-economic fallout, making it imperative and urgent to collaborate internationally to rapidly contain the outbreak.*

7. *As new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable price to meet global demand. Critical shortages in medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases.*

8. *To meet the growing supply-demand gap, several countries have initiated domestic production of medical products and/or are modifying existing medical products for the treatment of COVID-19 patients. The rapid scaling up of manufacturing globally is an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need.*

9. *There are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients. It is also reported that some WTO Members have carried out urgent legal amendments to their national patent laws to expedite the process of issuing compulsory/government use licenses.*

10. *Beyond patents, other intellectual property rights may also pose a barrier, with limited options to overcome those barriers. In addition, many countries especially developing countries may face institutional and legal difficulties when using flexibilities available in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). A particular concern for countries with insufficient or no manufacturing capacity are the*

> *requirements of Article 31bis and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products."*

70 A revised proposal was tabled on 21 May 2021 by South Africa, India, and a number of other delegations, including those of the African Group, the [Least Developed Country] Group, and various other developing countries. The revised proposal, a copy of which is attached as annexure **"AY18"**, remained particularly broad. This much is clear from paragraph 1 of the revised draft decision text:

> *"The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19."*

71 According to an article titled *"TRIPS waiver compromise draws mixed response"*, which was published by the global development community media platform Devex, the revised proposal drew *"the support of more than 100 countries and tentative backing from U.S. President Joe Biden's administration, though Washington limited its support to a waiver for vaccines."* A copy of the article dated 17 March 2022, written by Andrew Green, is attached as annexure **"AY19"**.

72 In a statement dated 5 May 2021, a copy of which is attached as annexure **"AY20"**, the US Trade Representative announced her government's support for a waiver in respect of Covid vaccines:

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> *"This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures. The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines. We will actively participate in text-based negotiations at the World Trade Organization (WTO) needed to make that happen. Those negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved."*

73 The outcome of the text-based negotiations bears little resemblance to what was put to member states for their consideration, whether in the original or amended waiver proposals. That said, the Ministerial Decision on the TRIPS Agreement, which was adopted by the WTO on 17 June 2022, paints an interesting picture regarding the global consensus on compulsory licensing being the public health flexibility of choice. A copy of the decision is attached as annexure **"AY21"**.

74 For starters, paragraph 9 of the June 2022 decision makes it plain that it adds to the rights that all member states already have under TRIPS:

> *"This Decision is without prejudice to the flexibilities that Members have under the TRIPS Agreement, including flexibilities affirmed in the Doha Declaration on the TRIPS Agreement and Public Health, and without prejudice to their rights and obligations under the TRIPS Agreement, except as otherwise provided for in paragraph 3(b). For greater certainty, this Decision is without prejudice to the interpretation of the above-mentioned flexibilities, rights and obligations outside the scope of this Decision."* (My emphasis)

75 In addition, paragraph 2 of the decision permits all developing country member states to invoke Article 31 of TRIPS, which deals with compulsory licensing, *"through any instrument available in the law of the Member such as executive*

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*orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place."* I am advised that such use would have to comply with domestic law.

76 Moreover, paragraph 3(b) of the decision allows all WTO developing country member states to issue compulsory licences without having to use the cumbersome Paragraph 6 system. This would apply in circumstances where Covid vaccines are manufactured in one developing country member, largely or exclusively for export to another developing country member. The Paragraph 6 system does not ordinarily apply if countries are largely producing for themselves.

**Domestic policy and law reform**

77 Despite significant international developments over many years, South Africa has yet to see anything vaguely similar to the nature and extent of legislative reform in countries such as Botswana, Malaysia, and New Zealand. Since the adoption of the Doha Declaration, our Patents Act has been amended on three occasions: by the Patents Amendment Act 58 of 2002, the Patents Amendment 20 of 2005, and by the Companies Act 71 of 2008.

78 Yet none of these amendments concerns either section 4 of the Patents Act, which empowers *"a Minister of State … [to] use an invention for public purposes"*, or section 56, the subject of the main application, which provides for the grant of a compulsory licence in the case of the abuse of rights in a patent. While section

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4 has never been amended, section 56 was most recently amended in 1997, purportedly to give effect to TRIPS. But it has yet to be reconsidered post-Doha.

79 Instead, the Department of Trade and Industry ("the dti"), now the Department of Trade, Industry, and Competition ("the dtic"), embarked on – but has yet to give effect to – a process of policy reform. On 3 September 2013, then Minister Rob Davies published the Draft National Policy on Intellectual Property, 2013 for public comment. As most of what is contained in that document is not relevant to this application, I only attach – as annexure **"AY22"** – a copy of the patent section of Chapter 1 (Forms of IP), and the whole of Chapter 2 (IP and Public Health).

80 After expressly mentioning the Doha Declaration, the 2013 draft policy makes the following two recommendations: first, that *"South Africa must change the Patents Act to incorporate patents flexibilities as contained in the TRIPS Agreement after the Doha Decisions"*; and second, that *"[t]he Patents Act should be amended to be amenable to issues related to access to public health."* Elsewhere, it states that the Act should be amended *"to address issues of … compulsory licensing in line with the Doha Decision of the WTO on IP and public health."*

81 It would take another five years before Cabinet finally adopted the Intellectual Property Policy of the Republic of South Africa Phase 1 ("the 2018 IP Policy"). As part of the lengthy dti process, TAC and its colleagues made three submissions:

81.1 First, a submission dated 17 October 2013 on the 2013 draft policy (with MSF and SECTION27);

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81.2 Second, a submission dated 30 September 2016 on the Intellectual Property Consultative Framework (as part of the FTPL campaign); and

81.3 Third, a submission dated 24 October 2017 on the revised Draft Intellectual Property Policy of the Republic of South Africa: Phase 1, 2017 (also as part of the FTPL campaign).

82 The 2018 IP Policy, relevant portions of which are attached as annexure **"AY23"**, summarises some of the history to which I have already referred. Significantly, it recognises the link between the PMA's challenge to Act 90 of 1997, and the adoption of the Doha Declaration, and makes it plain that the dti is firmly of the view that South Africa has yet to legislate to the full extent permitted by TRIPS:

> *"[T]he South African government has to date not made full use of the flexibilities available within international trade rules through the pursuit of appropriate national policy and legislation. This is despite a constitutional imperative to increase access to medicines as a component of the state's obligation to take reasonable measures toward the realization of the right to healthcare services. Indeed, this constitutional imperative is reflected in government policies such as the NDP and the National Drug Policy for South Africa."*

83 In introducing the section on compulsory licensing, the 2018 IP Policy states:

> *"South Africa's unique challenges, including especially vulnerable populations and urgent development concerns, will require the scope of compulsory licences to be strengthened and clarified in a manner that is fair and compliant in relation to both international obligations and national law. Following due process, guidelines will be introduced, including legal process for government use, and*

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*a renewed effort to facilitate the process of exporting IP goods, such as medicines, to the African continent."*

84 And insofar as the scope and importance of licences are concerned, it provides:

*"The TRIPS Agreement sets specific conditions for the use of compulsory licences. Even so, the Doha Declaration confirmed explicitly that 'each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.' Almost fifteen years later, the [United Nations Secretary General's High Level Panel on Access to Medicines] reiterated the importance of compulsory licensing and the sovereign right of states to make use of it, including ensuring the expedient use of compulsory licences or government use provisions."*

85 It is of great concern that what is contained in the 2018 IP Policy in respect of patents has yet to be translated into legislative amendments. This is despite a promise made by the Minister of Trade, Industry, and Competition, in his budget vote speech of 20 May 2022, that a draft Patents Amendment Bill would be submitted to Cabinet for consideration by October 2022. This was one of the *"concrete actions"* promised by the Minister. A copy of his speech is attached as annexure **"AY24"**.

**The relevance of TAC's new evidence, how it differs from the evidence of the parties, and how it will be of assistance to this Court**

86 As SECTION27 noted in its letter seeking consent for TAC and MSFSA to be admitted as *amici*, the evidence seeks to play a twofold role: first, to place TAC's and MSFSA's legal submissions in their relevant context; and second, *"to allow*

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*the Court to understand the broader ramifications of the relief sought by the applicants"*. In particular, the letter noted as follows:

> *"Our clients are of the view that knowledge of these historical events will ensure that the Court is well-placed to understand the key role that section 56 of the Patents Act may play in unlocking access to medicines, and what this may mean for its proper interpretation and application."*

87 I am advised that not only has the state never relied on the provisions of section of the Patents Act to *"use an invention for public purposes"*, but that no private party has ever successfully invoked the provisions of section 56. To date, there are only four reported judgments in South Africa dealing with applications for compulsory licences, with none of them being in the field of pharmaceutical products, let alone life-saving medicines:

87.1 *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another* 1996 BP 455 (CP), concerning a patent related to agricultural fungicides;

87.2 The SCA appeal in *Delta G Scientific (Pty) Ltd) v Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA);

87.3 *Sanachem (Pty) Ltd v British Technology Group plc* 1992 BP 276, concerning a patent related to agrochemical substances; and

87.4 *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd* 1992 BP 331, concerning a patent related to a device for a baby diaper.

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88 The most recent of these judgments, being the unsuccessful appeal in *Delta G Scientific*, dates back almost 25 years to September 1998, being more than three years before the adoption of the Doha Declaration (in November 2001). I submit that in such circumstances, the evidence in this affidavit is plainly relevant: it helps to provide the full context within which this Court is to interpret and apply section 56 of the Patents Act. Accordingly, the evidence will assist this Court.

89 The evidence also shows just how resource-intensive and time-consuming it has been for TAC, fighting drug by drug, to increase access to safe medicines of proven quality and efficacy. With this in mind, TAC is of the view that if a compulsory licence cannot be issued in a case such as this, where the patented medicine is not registered in South Africa, and can only be accessed via special authorisation at an exorbitant cost, then section 56 is wholly unfit for purpose.

90 Not only is TAC's evidence plainly different from the evidence contained in the founding papers, but it is unlikely to bear any resemblance to what is contained in Vertex's answering affidavit in the main application. Put differently, the type of evidence that TAC seeks to have admitted into the main record is precisely what one would expect of *amici*: evidence that is unlikely to be placed before the court by the parties to the litigation.

**SUMMARY OF THE LEGAL SUBMISSIONS TAC AND MSFSA INTEND TO MAKE**

91 In the letter seeking consent, SECTION27 noted that the legal submissions that TAC and MSFSA intend to make *"fall broadly into two related categories"*:

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> *"9.1. First, our clients wish to make submissions on how the denial of access to medicines may infringe the right to have access to health care services. This would include a focus on how and why access to medicines is an integral component of the right to have access to health care services, and the right of all children to have access to basic health care services. In particular, our clients' submissions will focus on how the Patents Act 57 of 1978 – if interpreted in a particular way – would limit access to medicines in an unconstitutional manner, and what this means for the proper interpretation of that Act, and the obligations it imposes on patentees.*
>
> *9.2. Second, recognising that the Court will be called upon to interpret the meaning and application of section 56 of the Patents Act, our clients wish to make submissions on how and why that provision ought to characterised as the type of legislative measure contemplated by section 27(2) of the Constitution (which the state is required to take to achieve the progressive realisation of the right to have access to medicines). In particular, our clients will seek to do so with reference to what is permissible under [TRIPS] (and related developments) what is required under international human rights law."*

92 In what follows below, I deal briefly these two categories of submissions.

**Access to medicines as part of the right to have access to health care services, and the right of all children to have access to basic health care services**

93 This first leg of the legal submissions will focus on the nature and extent of the health care rights contained in sections 27(1)(a) and 28(1)(c) of the Constitution, understood in light of the obligations imposed by section 7(2), which requires the state to *"respect, protect, promote and fulfil the rights in the Bill of Rights"*, and section 27(2), which compels the state to *"take reasonable legislative and other*

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*measures, within its available resources, to achieve the progressive realisation of each of these rights [in section 27(1)]."*

94 Part of this focus will include a consideration of the difference between the state's positive obligations in respect of the right to have access to health care services in section 27(1)(a), and the right that every child has to basic health care services in section 28(1)(c). While the former is subject to the internal limitations imposed by section 27(2), the latter is immediately realisable, to be interpreted in light of section 28(2), which provides that in every matter concerning a child, their best interests are of *"paramount importance"*.

95 In considering the right to health, the legal submissions will also include a focus on the right to substantive equality in section 9 of the Constitution, and what this means for the state's positive obligations in sections 7(2) and 27(2). This focus will be done mindful of the constitutional imperative to ensure equitable access to medicines for all, regardless of where a person accesses health care services, whether in the public or private sector.

96 These submissions will also be made mindful of the injunction in section 39(2) of the Constitution that *"[w]hen interpreting any legislation, … every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights."* TAC and MSFSA intend to advance the argument that when interpreting and applying section 56 of the Patents Act, this Court ought to do so in a manner that sees the provision as giving (partial) effect to the state's positive constitutional obligations in respect of sections 27(1)(a) and 28(1)(c) of the Constitution.

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**TRIPS, international human rights law, and the type of legislative measures contemplated by section 27(2) of the Constitution**

97 In order to assist in understanding the type of legislative measures that sections 7(2) and 27(2) may require the state to enact in ensuring access to medicines, TAC and MSFSA will consider two things: first, what is permissible under TRIPS, as clarified in the Doha Declaration and related developments; and second, what is required under international human rights law. This will be done mindful of the following injunction in section 233 of the Constitution:

> *"When interpreting any legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law."*

98 In dealing with South Africa's international human rights obligations, and how these have an impact on the type of legislative measures that are contemplated by section 27(2) of the Constitution, TAC and MSFSA will consider the following instruments and related documents:

98.1 Article 25(1) of the Universal Declaration of Human Rights ("the UDHR"), which provides in relevant part: *"Everyone has a right to a standard of living adequate to their health and wellbeing, including food, clothing, housing and medical care and necessary social services"*;

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98.2 Article 12(1) of the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), which recognises *"the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"*, and requires states parties – in Article 12(2) – to take particular steps *"to achieve the full realization of this right"*;

98.3 *General Comment 14 on the right to the highest attainable standard of health (2000)*, issued by the treaty-monitoring body of the ICESCR, which recognises – among other things – that access to medicines is a key aspect of the right to health in Article 12, that the state's duty to protect the right to health includes the duty to adopt certain legislative measures, and that the essential elements of the right to health include availability, accessibility, acceptability, and quality;

98.4 Article 24(1) of the Covenant on the Rights of the Child, ("CRC"), which entrenches a child's right to enjoy the highest attainable standard of health, further providing that no child shall be deprived of their right of access to health care services;

98.5 Articles 12(2)(b) and (c) of the CRC, which require state parties to take various appropriate measures, including by ensuring the provision of necessary health care to all children, and by combatting disease;

98.6 *General Comment 15 on the right of the child to the enjoyment of the highest attainable standard of health*, issued by the treaty-monitoring

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body of the CRC, which recognises – among other things – that the benefits that come from readily available technological advancements reach all children that need them;

98.7 Article 27(1) of the UDHR, which provides that everyone has a right to enjoy and to share in scientific advancement and its benefits;

98.8 Article 15(1)(b) of the ICESCR, which recognises the right of everyone to enjoy the benefits of scientific progress and its applications;

98.9 Article 15(2) of the ICESCR, which requires states parties to take steps towards the full realisation of this right, including those necessary for the diffusion of science;

98.10 *General Comment 25 on science and economic, social and cultural rights*, dealing with Article 15 of the ICESCR, which –

98.10.1 deals with the relationship between access to medicines and intellectual property, recognising that the right to benefit from scientific advancement is an *"essential tool for the realisation of other economic, social and cultural rights"*; and

98.10.2 affirms the Doha Declaration, recognising that state parties *"should use, when necessary, all the flexibilities of the TRIPS*

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*Agreement, such as compulsory licences, to ensure access to essential medicines".*

99 The UDHR constitutes customary international law, which – in terms of section 232 of the Constitution – *"is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament."* In terms of section 231(2) of the Constitution, the ICESCR and CRC – which have both been ratified by Parliament – are also binding on South Africa.

**HOW THESE SUBMISSIONS ARE RELEVANT, LIKELY TO BE DIFFERENT FROM THOSE OF THE PARTIES, AND WILL BE OF ASSISTANCE TO THE COURT**

100 The main application, which deals primarily with the proper interpretation of section 56 of the Patents Act, and how it ought to be applied in the particular set of troubling facts set out in the founding affidavit, concerns access to life-saving medicines, an integral part of the right in section 27(1)(a) of the Constitution to have access to health care services. What this means is that section 39(2) of the Constitution is in play, placing an obligation on this Court to *"promote the spirit, purport and objects of the Bill of Rights."*

101 Section 39(1)(b) of the Constitution makes clear that when interpreting the Bill of Rights, this Court *"must consider international law"*. The legal submissions that TAC and MSFSA seek to advance are designed to enable this Court to do just that – by being assisted to understand the relevant domestic constitutional and international law contexts within which the interpretive exercise is to be done.

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Accordingly, the contemplated legal submissions are both relevant to the issues to be decided in the main application, and are likely to assist this Court.

102 While none of the parties has yet to deliver their heads of argument, it is unlikely that any of their legal submissions will focus on the issues identified by TAC and MSFSA, either at all, or to the extent contemplated here. That said, both TAC and MSFSA are willing to ensure that their written submissions do not unnecessarily repeat any of the legal submissions contained in the parties' heads of argument.

**CONDONATION**

103 There are three reasons why TAC and MSFSA submit that condonation ought to be granted for the late filing of this application.

103.1 First, given the nature and age of much of the evidence included in this application, it was either not readily available, or needed to be subjected to an internal review process to confirm its accuracy. In addition, many of those with the requisite institutional memory are no longer directly involved with, or employed by, either organisation. Moreover, counsel for TAC and MSFSA, who has such institutional memory, was out of the country for half of March, and unavailable for a large part of the rest.

103.2 Second, any delay there may have been in bringing this application has caused no prejudice to the parties in the main application.

103.2.1 The applicants only filed their founding papers on or about 7 February 2023.

103.2.2 The respondent was due to file its answering affidavit on or about 7 March 2023. I do not know if that affidavit has been filed. I have yet to see any replying affidavit.

103.2.3 The matter has not as yet been set down for hearing, and the filing of this application has not delayed the further conduct of the main application in any way.

103.3 Third, given the nature and extent of the new evidence, as well as the legal submissions that TAC and MSFSA seek to make, granting condonation would be in the interests of justice, as it would assist this Court in its deliberations. If successful, the main application would result in the first grant in South Africa of a compulsory licence. A slight delay in the filing of this application, which prejudices no-one, ought not to result in this Court being deprived of TAC's and MSFSA's contributions.

104 In the circumstances, I submit that good cause has been shown for the grant of condonation.

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**CONCLUSION**

105 In the result, I submit that both TAC and MSFSA have made out a case to be admitted as *amici*, for their evidence to be included of the record in the main application, and for them to be granted leave to make both written and oral legal submissions in that application.

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

**ANELE YAWA**

I hereby certify that the deponent has acknowledged that he knows and understands the contents of this affidavit, and that it is to the best of his knowledge both true and correct. This affidavit was signed and sworn to before me at Johannesburg on this the 18th day of April 2023.

**COMMISSIONER OF OATHS**

BUSISIWE NDEBELE
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