South African Institute of Race Relations NPC
Submission to the
International Trade and Economic Development Division of the
Department of Trade and Industry,
regarding the
Draft Intellectual Property (IP) Policy of South Africa – Phase 1 (2017)
Johannesburg, 9th October 2017

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Introduction

The International Trade and Economic Development Division of the Department of Trade and Industry (the DTI) has invited public comment on the Draft Intellectual Property (IP) Policy of South Africa – Phase 1 (2017) (the IP policy). Public comment is due not later than 9th October 2017.

It would have been useful if the IP policy had been accompanied by an initial socio-economic assessment of its likely economic and other ramifications, as envisaged in the government's new Socio-Economic Impact Assessment System (SEIAS). Any future assessment of this kind, if it is to provide sufficient guidance, should take full account of all the issues raised in this submission. These range from the conflict between the DTI's proposals and binding international agreements on intellectual property rights to the likely ramifications of these proposals for the health care sector, the pharmaceutical sector, local innovation, and the wider economy.

This submission is made by the South African Institute of Race Relations NPC (IRR), a non-profit organisation formed in 1929 to oppose racial discrimination and promote racial goodwill. Its current objects are to promote democracy, human rights, development, and reconciliation between the peoples of South Africa.

Proposed changes and underlying policy objectives

The IP policy aims begins by acknowledging the importance of intellectual property (IP) in 'promoting innovation, technology transfer, research and development (R&D),…industrial development and, more broadly, economic growth'. It emphasises the importance of growth and jobs in reducing poverty and inequality, and stresses the need for South Africa to 'transition towards a knowledge economy', so as to end its over-reliance on natural resources. It also notes that Section 25 of the Constitution protects property of various kinds, including IP, and speaks of the need to develop a 'balanced' approach to IP that complies with the Constitution's requirements. In addition, it undertakes to 'implement commitments undertaken [by South Africa] in international agreements'.[1]

Unfortunately, however, many of the changes proposed in the IP policy will undermine, rather than advance, these important objectives. However, before proceeding to comment on the specific recommendations in the IP policy, a brief explanation of the rationale for the patent system and key patent rules in South Africa is needed.

South Africa's Patents Act and its TRIPS obligations

The property rights protected in most countries cover not only physical property, such as land or factories, but also intellectual property (IP) in the form of patents and copyright. The patent system is particularly important in promoting innovation because it gives inventors who are granted patent rights a 20-year period to make and sell their new products, without competitors being allowed to copy them. However, once a patent has expired, competitors are entitled to use the innovation, so making its benefits more broadly available.

In essence, the inventor – the patent holder – is given a 'window of opportunity' for the exclusive exploitation of his innovation. In return, he must make a full disclosure of his invention, the benefits of which, in time, become available to all. This system brings advantages all round: the patent holder is rewarded for his creativity, insight, and costly research and development (R&D), while everyone else can copy, sell, or otherwise use his innovation after 20 years. At the same time, because the invention is disclosed in the patent application, this creates the possibility of unauthorised copying and 'free-ridership', which patent laws seek to counter by providing various remedies against infringement.[2]

In South Africa, the granting of patents is governed by the Patents Act of 1978, which covers patents over medicines as well as all other innovations. Under its terms, patents are granted by the Patents Office – now the Companies and Intellectual Property Commission (CIPC) – and are then published in a 'patent journal', which is open to public inspection. Patents remain in force for 20 years from the date an application is lodged, even if the patent is granted only some time later. During this 20-year period, a patented invention may not be used, made, sold, or imported into South Africa without the consent of the patent holder. [3]

The basic requirements for the granting of a patent in South Africa (as in other countries) are novelty and utility. In essence, a patent may be granted under the Patents Act for any 'new' invention which involves 'an inventive step' and is 'capable of being used or applied in trade, industry, or agriculture'.[4]

Disputes over patents are adjudicated in a specialist court known as the Court of the Commissioner of Patents (the patents court). This follows the usual rules of civil procedure and functions in much the same way as other divisions of the country's high court. The commissioner of patents (the patents commissioner) is a judge of the Pretoria high court, whose sole function – despite a statutory title which may suggest something wider – is to hear and decide patent cases. These commonly range from objections to patents granted to applications for compulsory licences (as further explained in due course) and litigation to enforce patents against alleged infringements.[5]

South Africa is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was adopted in 1994 and entered into force the following year. This agreement is administered by the World Trade Organisation (WTO) and is binding on all WTO member states, including South Africa. It sets down minimum standards for the regulation of patents, which are enforced through the normal dispute settlement mechanisms of the WTO.[6]

The 'problem statement' in the IP policy

Though South Africa already has a sophisticated Patents Act, the IP policy states that the country still requires 'a comprehensive IP policy' that promotes local manufacturing, makes it easier for 'domestic industries and individuals to take advantage of the IP system', and deals with 'the intersection of IP and public health', which has 'long been an issue of contention'. [7]

Again, some background information is useful here. In the health sector, most patent applications are made by foreign pharmaceutical corporations or their South African subsidiaries. This is especially so in the context of HIV/AIDS, where life-saving antiretroviral medicines (ARVs) have generally been developed in the United States and Europe by pharmaceutical companies such as Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Hoffmann-La Roche, Merck, and Pfizer. Many of these companies, or their local subsidiaries, have sought and obtained South African patents to protect their innovations from being copied by generic manufacturers for the normal patent period of 20 years.[8]

In the early 2000s, as the HIV/AIDS pandemic in South Africa accelerated, health activists in the AIDS Law Project, the Treatment Action Campaign (TAC), and other organisations began to criticise the patent system for keeping the costs of ARVs higher than they would be if more generic competition was permitted at an earlier stage. They have repeatedly urged that the Patents Act be amended to take full advantage of the flexibilities included in international treaties: particularly the TRIPS Agreement and Doha Declarations, along with the '30 August Decision' of the General Council of the WTO.[9] (All these agreements are further described in due course.)

At the same time, however, the costs of researching and developing safe and effective new pharmaceuticals are high, especially as failed attempts inevitably far outnumber successes. In addition, writes Jasson Urbach, a director of the Free Market Foundation in South Africa: 'It often takes a decade to take a molecule through testing and regulatory approval – a process which begins only *after* a patent has been granted as no company will invest in an unpatented molecule. Most medicines thus have an effective patent term of approximately ten years. Given the huge investment required to bring a drug to market, this window of opportunity does not leave companies much time to earn adequate returns on their investments.' By contrast, as Canadian IP experts Ashley Weber and Lisa Mills note, 'the cost of imitation is relatively low, meaning that once a drug has been developed, it can be generically reproduced at a fraction of the cost'.[10] Patent rights are thus important in encouraging innovation and the development of new medicines against a host of ailments.

According to the 'problem statement' in the IP policy, much of the current tension between IP rights and public health care needs stems from the fact that South Africa does not conduct substantive search and examination (SSE) prior to the granting of patents. This, it says, results in a very high proportion of patents being granted, many of which 'would not pass muster under an examining system'. In addition, it says, South Africa is not yet 'taking full advantage' of the flexibilities allowed by the TRIPS Agreement to 'stimulate genuine innovation' while also 'promoting public health'.[11]

The IP policy thus seeks to introduce various changes to patent law in a 'phased approach'. The 2017 document, it says, 'constitutes the first phase in what will be a comprehensive policy to be developed and updated over the medium term'. This first phase, it adds, 'covers

IP and public health', along with co-ordination in international forums and 'the implementation of commitments undertaken in international agreements'.[12] However, this proposed focus on pharmaceutical and other health products is prima facie contrary to the non-discrimination provisions in TRIPS and is likely, especially given the content of the changes proposed, to put South Africa in breach of its commitments under this binding agreement.

The IP policy, like the DTI's 2016 IP Consultative Framework (the IP framework), and the department's yet earlier Draft National Policy on Intellectual Property, published in September 2013 (the draft policy document), is brief and often lacks the information needed to understand the full extent and likely ramifications of its proposals. To grasp the full import of the DTI's thinking, the IP policy needs to be read in the context of an article published by the United Nations Development Programme (UNDP) in October 2013, under the title 'Using law to accelerate treatment access in South Africa'.[13] This UNDP document (the UNDP article) was drawn up with significant input from the AIDS Law Project, an activist civil society organisation now known as Section27, and provides important further insights into what the DTI seemingly has in mind.

IP and public health (Section 7.1, IP policy)

The IP policy wants most of its proposed changes, at least at the start, to apply solely to patents in the health care sphere. However, this would be contrary to Article 27.1 of TRIPS, which states that 'patents shall be available for any inventions…in all fields of technology', and that 'patent rights shall be enjoyable without discrimination as to…the field of technology'.[14]

South Africa thus cannot adopt a different set of rules for patent rights in the health sphere. Moreover, though the IP policy indicates that patent rights may be limited in the interests of public health, it is selective in its description of what the Doha Declarations provide.[15]

These declarations were adopted in 2001 at a WTO ministerial conference in Doha on health and other matters. This culminated in the adoption of a wide-ranging Doha Declaration, which deals briefly with health (among a host of other issues), and stresses the importance of 'implementing and interpreting the TRIPS Agreement in a way that supports public health – by promoting *both* access to existing medicines *and the creation of new medicines*'. However, the declaration's emphasis on the need also to 'promote…the creation of new medicines' is overlooked in the IP policy.

The same dual emphasis is evident in a supplementary Doha Declaration on 'The TRIPS agreement and public health', which was adopted at the same time. This says that TRIPS 'does not and should not prevent member states from taking measures to protect public health', while recognising that both access to existing medicines and the creation of new medicines are important. This document reaffirms their 'ability to use the flexibilities' built into the TRIPS Agreement, so as 'to promote access to medicines for all', but it does not sanction measures going beyond these flexibilities. In addition, while acknowledging

concerns regarding the prices of patented medicines, the declaration also 'recognises that intellectual property protection is important for the development of new medicines'.[16]

The IP policy misquotes the Doha declarations, for it overlooks the extent to which these documents require countries to support public health – not only by promoting access to existing medicines – but also by 'promoting the creation of new medicines' and 'recognising that intellectual property protection is important for the development of new medicines'. It is particularly misleading in the way it cites the Doha Declaration on TRIPS and Public Health. The IP policy takes care to include that part of the Declaration which urges 'access to medicines for all', but it omits the provisions which recognise that 'intellectual property protection is important for the development of new medicines'.[17]

The IP policy also stresses that 'the South African government has to date not made full use of the flexibilities available within international trade rules through the pursuit of appropriate policy and legislation'. It thus seeks to make greater use of TRIPs flexibilities to reduce the patent protections currently available for medicines and other health products, including 'vaccines and diagnostics'.[18] However, this selective focus on health patents is itself problematic. Often, moreover, its proposals for change go well beyond what the TRIPS Agreement allows, as further described below.

In attempting to justify its initial focus on health care patents, the IP policy emphasises the constitutional right of access to health care in Section 27 of the Bill of Rights. According to this provision, 'everyone has the right to have access to health care services', while 'the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of this right'.[19] According to the IP policy, this provision means that the government has 'a constitutional imperative to increase access to medicines'.[20] However, the state is also obliged to take 'reasonable' measures in fulfilling its obligations under Section 27 – and abrogating its binding treaty obligations is not a 'reasonable' way of increasing access to medicines, especially when better methods are available. In addition, the state is obliged to act within 'the limits of its available resources' and must respect this constraint, rather than seeking to circumvent it by undermining and breaking patent rights.

The IP policy (in *Section 4, Purpose*) also attempts to justify its focus on health patents by citing the property clause in the Constitution. According to the IP policy, the property clause (Section 25) requires 'a balanced approach' to property rights, which both 'protects against arbitrary deprivation of property' and 'takes account of the public interest'. However, the document is again misleading in the way it describes 'the public interest'. According to the IP policy, 'the public interest includes the nation's commitment to bring about reforms that promote equitable access to services and products involving IP, such as in the sphere of health'.[21] But much of this is a fabrication. Section 25 of the Constitution in fact defines the public interest as including 'the nation's commitment to land reform, and to reforms to bring about equitable access to all South Africa's natural resources'.[22] By leaving out these references to land reform and the country's natural resources – and replacing them with

wording about IP in the health sphere – the IP policy significantly distorts the meaning of the property clause.

Local manufacture and export (Section 7.1.1, IP policy)
According to the IP policy, 'the pharmaceutical industry is one of the priority sectors identified by IPAP' or the DTI's Industrial Policy Action Plan. It also notes that 'the contribution of this industry to South Africa's GDP has declined from 1.6% to 1.1% over the past six years'. The sector nevertheless still provides approximately 10 000 direct jobs and another 25 000 indirect ones, the document adds.[23]

The IP policy estimates the worth of the local pharmaceutical market at R40bn, and describes it 'as the largest in sub-Saharan Africa'. It notes, however, that South Africa's pharmaceutical sector remains small by international standards, 'constituting a mere 0.4% and 1% of the global market by value and volume respectively'. It also stresses that '65% of the domestic demand for pharmaceuticals, by value, is met by imports', with the result that 'medical products are the fifth largest contributor to South Africa's trade deficit'.[24]

The IP policy thus claims that 'there is tremendous potential for this sector to grow and contribute value-added jobs to the South African economy'. Increasing domestic production, it adds, will 'ensure our security of supply, given, inter alia, that the country's unique disease burden necessitates drugs formulated using specific active pharmaceutical ingredients (APIs) of which global supply is limited'.[25]

The IP policy thus suggests that health care patents are a key barrier to the growth of a local pharmaceutical industry, when this is not the case. Far more relevant are a host of other obstacles, ranging from poor skills and limited productivity to electricity shortages, fractious labour relations, limited logistics, and high input costs of various kinds. Making it easier and cheaper to copy patented medicines and other health products will do little to overcome these problems. Instead, it will reinforce perceptions that the government is hostile to business and the free market, giving potential direct investors more reason to bypass the country.

In addition, it will not be easy to revive South Africa's pharmaceutical industry when this has been shrinking rather than expanding over the past two decades. Since 1994, some 35 pharmaceutical factories have shut down, while the number of people employed by the industry has shrunk from 16 000 in 2000 to 11 000 in 2007,[26] and now stands lower still at 10 000, as the IP policy notes.[27]

Moreover, much of the reason for this decline lies in the government's own policies. The introduction in 2004 of stringent price controls on medicines, via the 'single exit price' mechanism, has been particularly damaging, for the Department of Health has repeatedly refused to allow these regulated prices to increase in line with inflation, rand weakness, and rising production costs.[28]

These rigid price controls have greatly eroded the profitability of the remaining pharmaceutical manufacturers. In 2008 an analyst for the research house Frost & Sullivan described South Africa's pricing regulations as 'disgraceful'. He noted that a number of foreign firms had already withdrawn from the country and predicted that many others would follow suit. 'What's been going on has made the international community look with jaundiced eyes and dampens prospects for foreign investment,' he added.[29]

Since 1994, the state has also subjected pharmaceutical (and other) companies to a barrage of 'transformation' requirements that are not only difficult and costly to fulfil but also continually in flux, making adequate planning and implementation still harder to achieve. At the same time, the quality of education in South Africa has remained very poor (despite budgeted revenues exceeding 6% of GDP), so skills have remained in short supply while the growing inefficiency of government has become a major burden to business in every sphere.

The IP policy document differs from its predecessor (the 2016 IP framework) in that it makes no mention of 'Project Ketlaphela', the government's attempt to establish a state-owned pharmaceutical company. In its 2016 document, the DTI saw this state-owned company as playing a vital role in the manufacture of the active pharmaceutical ingredients (APIs) needed in anti-retroviral and other medicines – and which were reportedly in short supply around the globe. In time, the IP framework added, Ketlaphela would also engage in tablet formulation and start expanding into the SADC region. This, it claimed, would be 'key to improving the domestic component of the supply of ARVs and improving security of supply both domestically and sub-regionally'. [30]

However, South Africa's experience to date with its state pharmaceutical company is not encouraging. In 2007, at the Polokwane national conference that elected Jacob Zuma as president of the ANC, the ruling party resolved to 'explore the possibility of a state-owned pharmaceutical company that intervenes in the curbing of medicine prices'. In 2012 this state-owned firm, called Ketlaphela, was finally established. Five years later, however, it has yet to assume operations or even to complete the construction of a pilot plant. [31]

Ketlaphela was initially a joint venture between the state-owned fluorochemical producer Pelchem – a subsidiary of the South African Nuclear Energy Corporation – and a Swiss company, Lonza Pharmaceuticals. However, Lonza withdrew from the venture in 2013 and the government has been unable to find alternative investors. (Four other potential partners initially expressed interest, but pulled out because they did not think the project was commercially viable.)[32]

Ketlaphela (a Sesotho word meaning 'I will survive') has long been intended to manufacture the APIs needed in the production of ARVs. It was initially expected to start producing APIs in 2016, but officials in the Department of Science and Technology now see 2019 as a more likely start date.[33] Ryan Lobban, a healthcare analyst at Frost & Sullivan, has also cautioned against these plans, saying: 'Manufacturing APIs is a sophisticated business. It requires special skills. The set-up costs are very high.' The manufacturing of APIs is also a low-

margin business, which Western pharmaceutical companies often outsource to low-cost producers in countries such as India and China. Hence, Ketlaphela will consistently have to beat these established and experienced producers, on both cost and quality, if it is to persuade local pharmaceutical companies to shift away from their Asian suppliers.[34]

Whether Ketlaphela will succeed in this is doubtful. Already, many of South Africa's state-owned enterprises – including long-established ones such as Eskom, the South African Airways, the Post Office, and the South African Broadcasting Corporation – are poorly managed, singularly inefficient, and heavily dependent on billions of rands in bail-outs from the fiscus. Ketlaphela is unlikely to do better.

According to the ANC-aligned National Education Health and Allied Workers' Union (Nehawu), Ketlaphela offers 'the most sustainable way of expanding domestic production' and 'the best way to keep the costs of medication down' because, unlike private firms, it will not be trying to 'commodify and prolong sickness'.[35] However, these claims are based more on optimism and ideology than on the record to date of either Ketlaphela or the country's other SOEs.

The IP policy (like the earlier IP framework) claims that the pharmaceutical sector has enormous potential to expand and generate jobs'.[36] However, it will battle do so in an economy confronting low growth, high inflation, limited business and consumer confidence, increasing threats to property rights, and a host of further obstacles to success. In addition, even if Ketlaphela manages to start production, it is unlikely to succeed in reducing the costs of medicines or generating many new jobs.

In the words of Tony Carroll, senior associate at the Centre for Strategic and International Studies (CSIS) in Washington DC, many countries on the African continent have tried to insist on domestic production and import substitution, but generally with 'woeful' consequences that include 'high prices, lower quality, and the creation of economic oligarchies often utilising nefarious tools to lock up their market share'. Even in the best of circumstances, moreover, domestic manufacturing does little to bring down the costs of medicines, which are driven up mostly by the costs of 'research, drug trials, education and marketing', while production costs make up only 25% of the total. The pharmaceutical manufacturing business is also capital-intensive and has little need for labour (particularly the unskilled labour in which South Africa abounds). 'To build a plant that meets minimum safety standards, modern facilities and processes – which are very mechanized – must be constructed,' cautions Carroll.[37]

At the same time, if Ketlaphela and other pharmaceutical manufacturing companies are to achieve economies of scale, they will have to go beyond South Africa's borders and successfully tap into a wider continental market that could be worth around $45bn by 2020. However, such expansion will be difficult to achieve when South African companies confront a heavy regulatory burden and many other constraints on their competitiveness. In addition, in any contest for market share in the rest of Africa, South Africa will battle to compete with

India, in particular, which has a well established generics industry, better skills and productivity, and significantly lower labour and other input costs.[38]

Substantive search and examination (Sections 3 and 7.1.2, IP policy)
The basic requirements for the granting of a patent in South Africa, as in other countries, are novelty and utility. In essence, as earlier noted, a patent may be granted under the Patents Act for any 'new' invention which involves 'an inventive step' and is 'capable of being used or applied in trade, industry, or agriculture'.[39]

The key issue for present purposes is that South Africa is a 'depository' or 'non-examining country', in which all patent applications made to the Patent Office – now the CIPC – are granted, provided a detailed patent 'specification' (or description of the invention) is provided and the necessary fees are paid.[40] In various other countries, by contrast, all patent applications are examined for their novelty and utility before patents are granted.

Critics of the depository system claim that the absence of prior examination inevitably leads to the granting of 'weak' or 'frivolous' patents that do not satisfy the relevant requirements or merit protection. According to the IP policy, this has 'substantial drawbacks for both producers and users of IP. For producers, the lack of examination calls into question the integrity of their patents,…[while] users of IP are prejudiced…because subject matter that should be in the public domain is unfairly monopolised by exclusive rights'. Moreover, the granting of patents where there has been no genuine innovation undermines the essential bargain that underpins patent law and 'short-changes society'.[41]

The IP policy also claims that 93% of the patents applied for in South Africa are granted, as opposed to 61% in the US, 51% in the European Union (EU), and 29% in Japan.[42] This analysis is flawed, however, for the figures cited are taken from a recent article by Bhaven Sampat and Ken Shadlen, which deals solely with the granting of pharmaceutical patents. Hence, the Sampet and Shadlen figures do not relate to patents in general, but only to pharmaceutical ones. The pharmaceutical patents they analyse are also of a particular kind, for they are secondary patents dealing with incremental improvements, such as new uses of existing molecules or new forms of existing compounds. Such patents may perhaps be granted more easily in South Africa than elsewhere, but South Africa's Patents Act prevents them from extending the terms of the patents initially granted. Here, such incremental improvements are protected by 'patents of addition' (as further described below), which expire at the same time as the original patents and cannot be used 'ever-green' patent terms.

The IP policy also goes on to claim that comparable patent grant rates in India and Brazil are 19% and 14% respectively. Again, however, this is not so,[43] for the comparable figures cited by Sampet and Shadlen are in fact 41% for India and 5% for Brazil. The very low grant rate in Brazil is a product of 12- to 14-year delays in the examination of patents, which results in many applications being abandoned or withdrawn.[44]

Other data on the granting of patents in South Africa, as compiled by the World Intellectual Property Organisation (WIPO), also paints a different picture. According to WIPO's most recent statistical country profile of South Africa, the number of patent applications made within the country, by both residents and non-residents, in the 15-year period from 2001 to 2015, totals some 107 000, giving an average of roughly 7 130 a year. The number of patents granted in the country over the same period, to both residents and non-residents, amounts to about 54 800, or roughly 3 650 a year, on average. This gives an average grant rate over this 15-year period of 51%.[45]

The key issue, moreover, is not the proportion of patent applications which succeed in South Africa, but rather whether the patents granted here are indeed as weak and unworthy of protection as the DTI and health activists commonly claim. This is by no means clear.

To begin with, the depository system does in fact have important safeguards, for it puts pressure on all applicants to ensure that no similar patent already exists. If an earlier patent for essentially the same invention subsequently comes to light, the later patent is invalid, the money spent on its development is wasted, and damages for infringement may also be payable.

Rowan Joseph, an intellectual property lawyer based in Cape Town, points to another safeguard, saying: 'The absence of patent examination in South Africa sounds bizarre, but it actually works because the examination system is the same throughout the world.' Hence, if an invention has been patented in the United Kingdom under the examination system in operation there, it will qualify to be patented in South Africa as well. Moreover, given the fact that virtually all developed economies have examination systems and most patents registered in South Africa come from developed countries, it makes little sense for South Africa to duplicate the procedures in operation elsewhere.[46]

Particularly relevant in this regard is the fact some 90% of patent applications in South Africa are filed by non-residents, most of which are multinational corporations (pharmaceutical or other). Moreover, almost all of these non-resident applications entering into the national phase in South Africa are international filings under the Patent Co-operation Treaty (PCT).[47]

The PCT, which entered into force in 1978 and is administered by the International Bureau of WIPO, makes it easier to obtain patent protection in any or all the PCT's member states. It provides for the filing of one patent application ('the international application') with effect in several states. It does not eliminate the need for the applicant to seek national patents, in the national phase of processing, before the patent offices of the countries in which he wants protection. However, it does make the national process easier in various ways. This is mainly because of the stringent procedures carried out during the international phase.

These procedures include a check on formalities and an international search, along with an (optional) supplementary international search and an (optional) international preliminary examination. In addition, since the international application establishes an initial filing date

which applies in all national processes, the applicant has more time and a better basis for deciding in what countries to pursue the application in due course. On completion of the various steps in the international phase, the applicant must still seek patents in the various countries (or regions) he has chosen. In this process, these national (or regional) patent offices will examine the application in the light of all the information the international process has generated. They will then decide whether to grant or refuse the national patent in their countries.[48]

As WIPO further explains, 'international applications under the PCT are subject to international search by International Searching Authorities and, upon request by an applicant, to international preliminary examination by International Preliminary Examining Authorities. Those Authorities are patent offices whose expertise in the matter of searching and examining patent applications is generally recognised. These Authorities issue the PCT International Search Report, Written Opinions, and International Preliminary Reports on Patentability.' These PCT reports provide national patent offices with a wealth of technical information relating to the inventions in question. These reports are not binding on national patent offices, but are nevertheless very useful in determining the patentability of inventions in different countries during the national phase. Since most patents granted in South Africa start with PCT international filings which are subjected to this high level of scrutiny, this 'increases the likelihood of granting high quality patents' in South Africa itself.[49]

In addition, as Mr Joseph points out, many of the non-resident applicants who seek patents from South Africa not only use the PCT system but also seek patents from countries and regions (the UK, the US, and the EU) which have their own rigorous examination systems. This adds to the scrutiny to which most of the patent applications granted in South Africa are subjected. Hence, the patents granted here should not be dismissed as weak and undeserving of protection.

By contrast, there is a real risk that, if South Africa insists on introducing full examination for patent applications, it will lack the capacity to carry out this process efficiently and timeously. According to the WIPO Policy Guide to Patent Examination, 'making decisions on patentability accurately, effectively, and efficiently is a complex mission'. Hence, 'a patent office needs significant financial and human resources to conduct search and examination by itself. A high degree of technical and legal expertise – not only to understand the technical aspect of inventions, but also to interpret the legal scope of patent claims and to analyse their compliance with the legal requirements prescribed in a patent law – is required to carry out a full…patent examination'.[50]

It is also important to recall that South Africa used to have an examination system but had to abandon it in 1978 because it lacked the necessary skills. In the words of Judge Louis Harms, a retired judge president of the Supreme Court of Appeal: '[South Africa] had an examination system from 1952, but we had to abolish it in 1978 because we never had the people to do [the job]. It's highly specialised. You need [a person who is both] a scientist and a lawyer, and will also do the job at a government salary.' [51]

According to a recent report in *City Press*, the CIPC has already trained 18 people as patent examiners. (Since the DTI is still seeking public comments on whether a substantive examination system should be introduced, this suggests that the DTI has little interest in the public consultation process and is simply going through the motions.) In the words of agency spokesman Tshiamo Zebediela, with these 18 individuals in place, the CPIC 'expects to handle a workload of 1 000 patent examinations in a year'. But South Africa receives more than 7 000 patent applications in every year,[52] raising questions as to how the remainder will be handled.

According to the IP policy, the answer lies in the fact that substantive examination will initially be confined to pharmaceuticals and various other 'strategic sectors'.[53] But the DTI's main concern is clearly 'the intersection of IP and public health', which means the focus of examination is likely to fall primarily on patents in the health sphere. Hence, it is the patent applications lodged by international pharmaceutical corporations that will primarily come under scrutiny. This means that the CPIC's 18 newly-trained examiners will often be duplicating the work that is already being done by the PCT and other experienced patent offices in the UK, EU, US, and so on, where these companies are likely also to have sought patents. South Africa could, of course, enter into co-operation agreements with these countries to help ease the burden, but this raises questions as to the value of its insisting on its own examination process when its capacity is so limited and the costs of examination will inevitably be high.

To cite the WIPO policy guide once again, for countries with limited skills 'there is an opportunity cost in not being able to employ highly skilled scientists and engineers in R&D in national priority areas'. In addition, 'a sufficient technical infrastructure (such as data bases) needs to be maintained in a patent office to conduct a prior art search'.[54]

At the same time, if a weak patent is wrongly granted under South Africa's current depository system, then competitors or would-be generic manufacturers can always apply to the patents court to have the patent set aside. Alternatively, a challenge to the patent can always be lodged by an alleged infringer if any attempt is made to enforce the weak patent against it. Notes the WIPO policy guide: 'The [depository] system defers substantive examination on patentability until a patent is actually litigated… The patentability requirements are [then] evaluated by a [specialist] court with respect to commercially relevant inventions only. This framework leads to considerable cost-saving in the patent office's spending, allowing the country to allocate its resources to other priorities.' The disadvantage is that the courts have to 'deal with the correction of erroneously granted patents, while patent owners and third parties must bear a greater uncertainty as to the validity of the patent, as well as litigation costs'. However, 'if the number of court cases is very small, then shifting the costs of evaluating the patentability of inventions to the post-grant phase may lead to an efficiency gain for the society at large'.[55]

Given the fact that some 90% of patent applications in South Africa are non-resident ones which are in any event subject to rigorous PCT and national examination elsewhere, the costs of examination here are likely far to outweigh its benefits. In addition, as patent attorney David Cochrane of Spoor & Fisher points out, such limited benefits as there might be in moving to an examination system are likely to be negated by poor implementation. Says Mr Cochrane: 'The biggest risk...is whether we have the capacity and the ability to implement it. A patent examination system will require graduates who have engineering and science degrees, and these graduates will have to undergo expert training to become patent examiners. If there are not enough patent examiners, or if they are not properly trained, this could lead to bad patent examinations...and long delays before patents are granted, [which could see] the whole patent system fall apart.'[56]

In practice, even if confining examination to pharmaceuticals (and other 'strategic sectors') enables South Africa's patent system to avoid such a collapse, the mooted change will add significantly to the costs and complexities in obtaining health patents. Ironically, the burden will fall most heavily on local inventors lacking the experience to navigate the new requirements. By contrast, multinational corporations will find it easier to cope because they are already well versed in the examination procedures in other countries and are likely to have more resources to draw on.[57]

The Innovative Pharmaceutical Association South Africa (Ipasa), which represents 26 of the world's leading global pharmaceutical research and biotechnology companies, supports the introduction of substantive patent examination in South Africa – provided this is accompanied by adequate resources and is TRIPS-compliant on patentability criteria and other issues. But Ipasa also cautions that failure to provide adequate human resources and IP infrastructure could result in long delays in dealing with patent applications. Brazil, it says, is 'experiencing an acute patent backlog (as long as ten years) as a direct result of an overwhelmed, resource-constrained SSE system'. Sampat and Shadlen report an even longer waiting period in Brazil, which they put at between 12 and 14 years. They also note that many applications filed there are simply abandoned or withdrawn. This is the key reason Brazil's rate of granting patents is so low: 0.5% as regards pharmaceutical patents in the period covered by the Sampat and Shadlen study, and 14% for patents of all kinds in 2015, according to the IP policy. In India, says Ipasa, 'the situation is a little better, but not satisfactory, for it takes an average of six years to secure a patent'.[58]

(Ipasa's 2016 submission thus recommends that SSE for domestic filings should initially be confined to 'areas where South Africa has strong technological capacity (mining, mechanical and agricultural technology)'. It also urges that foreign filings should be handled on the Singapore SSE model, where reliance is primarily placed 'on a positive foreign search and examination report from an approved examination authority', with only 'supplemental' examination by the Singapore patent office itself.)[59]

Given South Africa's skills shortage and the general inefficiency of state institutions, the great risk is that the introduction of an examination system, even along the lines suggested by

Ipasa, will generate long delays in the granting of patents. This will make it more difficult for all applicants, whether local or foreign, to obtain patents within a reasonable time. This will reduce the normal period of patent protection (20 years from the date of filing the application, not the granting of the patent) to something significantly shorter. This in itself – apart from all the other damaging changes proposed – is likely to become a major barrier to local innovation.

The supposed 'ever-greening' problem

The IP policy does not overtly deal with this, but the underlying purpose of its proposal is clearly to halt what health activists have long described as the common practice by pharmaceutical companies of 'ever-greening' their patent rights.

The UNDP article claims that pharmaceutical companies often obtain new patents on the basis of trivial improvements to their existing medicines, or by putting forward new forms of existing substances. However, a new form of an existing medicine (a syrup version of nevirapine, for instance) does not warrant patent protection if it has no additional therapeutic efficacy, but simply makes it easier to store, manufacture, or administer the drug. According to the UNDP article, pharmaceutical companies nevertheless often obtain new patents on the basis of such inconsequential improvements to their existing medicines.[60]

The Treatment Action Campaign (TAC), a South African civil society organisation with links to Section27, has weighed in on this issue too. As part of its 'Fix the patent laws' initiative launched in November 2011 (the tenth anniversary of the Doha Declaration on TRIPS and public health), the TAC argues that pharmaceutical companies commonly 'ever-green' their patents by 'developing new formulations...and new forms of existing medicines', which in fact offer 'nothing new' and 'have no therapeutic benefits'.[61]

A wider 'Fix the Patent Laws Campaign' continues to make similar claims. According to this coalition, which includes the TAC and various other health organisations: 'South Africa's legal framework for patents makes it too easy for pharmaceutical companies to extend their monopoly period on drugs…by applying for multiple patents on individual medicines over time – a tactic known as ever-greening.' It blames this phenomenon on 'shortcomings in South Africa's laws' and particularly on 'the lack of examination for patent applications', as the coalition told the media in September 2016.[62]

However, this criticism by the TAC and the wider coalition overlooks the clear wording of the South African Patents Act. This statute allows the granting of 'patents of addition' for any 'improvement in or modification of' an initial patented invention. However, it also states that a patent of addition expires at the same time as the original patent.[63] Hence, the original patent term cannot be 'extended' in South Africa through minor improvements in the way the TAC and the Fix the Patents Law Campaign suggest.

Moreover, even if a second patent is wrongly granted for an improvement or modification too inconsequential to warrant this, there is nothing in South African law to prevent the copying

of the initial version once the first patent has expired. But health activists seem to disregard this option.[64] In addition, the validity of a second patent granted in these circumstances can always be challenged in the patents court.

Health activists also overlook the fact that finding new uses or new combinations of existing molecules can be extremely useful in the treatment of disease. Finding a new use, for instance, also requires significant innovation in developing the new treatment, along with comprehensive laboratory research to test its likely efficacy, the usual clinical trials to confirm its effectiveness and safety in the field, and the normal complex process of obtaining regulatory approval for its marketing and sale.

According to Ipasa (in its 2016 submission to the DTI on the IP framework), 'patents provide critical incentives to invest [both] in "breakthrough" treatments and "incremental" improvements to existing medicines'. Health activists assume that all incremental improvements are suspect, but this is not so. Notes Ipasa: 'Nearly 25 per cent of illnesses are treated by medicines initially developed to address a different disease or condition, and more than 60% of the therapies on the World Health Organisation's (WHO's) Essential Medicines List relate to improvements on older treatments.' This is also not surprising, for knowledge and understanding are generally built up in incremental stages. In addition, the outbreak of a new disease, such as HIV/AIDS, is likely to prompt consideration of whether a molecule initially used for a different purpose might not, with appropriate modifications, be useful against the new disease as well.[65]

Ipasa adds that '80% of the world's patent applications are handled in five jurisdictions, one of which is China. All these major patent systems recognise the importance of incremental innovations and allow claims to subsequent medical uses for a known substance'. It urges South Africa to follow international best practice in this regard. It also warns that 'any national IP system that fails to recognise the important role played by incremental innovation will ultimately prevent innovators from realising the economic value of important inventions and also reduce the incentives for the development of local innovation-based pharmaceutical industries'.[66]

Patent Opposition (Section 7.1.3, IP Policy)

According to the IP policy, South Africa's patent law should be changed to allow a pre-grant observation mechanism, to be followed in due course by the introduction of a pre-grant opposition system. The policy also seeks changes – which it fails fully to define – to the country's existing system of post-grant opposition.[67]

The IP policy claims that pre-grant observation and opposition proceedings have various advantages, as they bring extra 'information and expertise to bear' in the examination process, 'encouraging domestic investors to increase their technological expertise' and 'limiting the need to engage in time-consuming and expensive patent revocation proceedings'.[68] However, as an international patent lawyer has pointed out, the PCT process, particularly in its international phase, is likely to yield significantly more technical and other

expert information than local activists may be able to muster. In addition, the hearing of objections prior to the grant is unlikely to be any less costly or time-consuming than the hearing of objections thereafter, if these should be lodged.[69]

According to the IP policy, *a 'third-party observation mechanism'*, which allows interested third parties to submit information relevant to the granting of a patent, is the least 'resource-intensive' for the government and should immediately be introduced. This would give 'all self-identified parties [the right] to make written submissions opposing the grant of any particular patent'.[70]

Though the IP policy does not spell this out, the underlying aim is seemingly to give Section27, the TAC, and other activist civil society organisations the capacity, not simply to observe, but in practice to object, to the granting of certain patents, thereby making it more difficult for these applications to succeed. Yet, as WIPO notes, an observation system is simply intended to provide additional information for a patent examiner to take into account.[71] In South Africa, however, patent examiners with limited experience and expert knowledge may too easily be persuaded by unfounded or misleading activist submissions to refuse the granting of patents for innovations that in fact merit protection.

The IP policy further proposes that, in time, pre-grant observation should be supplemented by the introduction of *pre-grant opposition proceedings*, 'once the minister of trade and industry is satisfied that there is sufficient capacity within the substantive examination system to make appropriate use of such proceedings'. Activist organisations would be granted the legal standing to participate in such proceedings. The IP policy also speaks of 'putting in place an administrative procedure' for this purpose.[72] Presumably, what it has in mind is that pre-grant opposition proceedings should be heard by the DTI's proposed Intellectual Property (IP) Tribunal. This is to be established under the Copyright Amendment Bill of 2017, but is to be given jurisdiction to hear all IP-related matters (not only those relating to copyright issues). However, there are many constitutional and other objections to the proposed IP Tribunal, as further described in due course.

Ipasa has cautioned against the introduction of a pre-grant opposition process, saying this 'risks introducing substantial delays and additional costs for patent applicants'. Delays could also limit the capacity of applicants to enforce their legitimate rights. The IP policy claims that any resulting burden on the state will be reduced by 'harnessing available information and expertise relevant to the…patent' in issue, which the DTI presumably plans to obtain from activist groupings. However, properly evaluating all the information made available by both activists and applicants will still be a demanding, complex, and time-consuming process. In addition, the longer the resulting delays last – and the more patent applications are rejected on spurious grounds – the harder it will be for South Africa to promote innovation, attract investment, or generate the growth and jobs that it so badly needs, below).[73]

There is also no need for a new *post-grant opposition system* when the current Patents Act already provides for this. Section 44 of this statute allows the granting of a patent to be

challenged before the patents court within nine months (or such longer period as may be allowed, on good cause shown). The IP policy makes no attempt to explain why the existing system needs to be changed. It speaks of the need to 'develop internal capacity and expertise' to handle proceedings of this kind, while overlooking the fact that the patents court already has all the necessary competence.

There is also no need, as the IP policy further proposes, for post-grant oppositions 'to proceed by way of administrative review' under the Promotion of Administrative Justice Act (PAJA) of 2000, until such time as 'the contemplated system of post-grant opposition is…in force'. [74] Administrative review is not an adequate substitute for the post-grant opposition proceedings already available via the patents court. There are also many constitutional, TRIPS-related, and other objections to removing the adjudication of post-grant objections from the patents court and vesting it (as the IP policy seems to envisage) in the proposed IP tribunal.

Patentability Criteria (Para 7.1.4, IP policy)

The IP policy further criticises the depository system for making it difficult for South Africa to use the flexibilities that TRIPS supposedly allows in the setting of criteria for patentability. According to the policy, various provisions in TRIPS give South Africa a right to 'interpret and implement the patentability requirements in a manner consistent with its constitutional obligations, developmental goals, and public policy priorities'. [75] It claims that this flexibility is to be found in Article 27.1 of the TRIPS Agreement, read with Articles 7 and 8. Again, however, the IP policy is misleading as to what TRIPs requires and allows.

The IP policy asserts that Article 27.1 'affords WTO members much flexibility when setting patentability criteria'. It then goes on: 'While [Article 27.1] requires that patents be granted for inventions that are new, involve an inventive step, and are capable of industrial application, it does not detail what is meant by these requirements. Instead, the footnote to the provision merely states that 'the terms "inventive step" and "capable of industrial application" may be deemed by a member to be synonymous with the terms "non-obvious" and "useful" respectively.'[76]

The IP policy suggests that, because Article 27.1 offers no further definition of these criteria, this means that the requirements for patentability may be modified by member states as they see fit. This is not so. The terms used in Article 27.1 (including the alternatives to which the footnote refers) are terms of art which have clear meanings in patent law. Applying these criteria may be difficult in practice – which is why patent examiners need a very high degree of technical and legal expertise – but the basic requirements of novelty and utility are well settled. They have also been further buttressed by their inclusion in the TRIPS Agreement.

The IP policy also overlooks important further wording in Article 27.1. Article 27.1 states that 'patents shall be available for any inventions…in all fields of technology' provided they comply with the basic requirements (ie, provided they are new, involve an inventive step and are capable of industrial application). This wording is peremptory, rather than permissive. The Article then goes on to say that 'patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether

products are imported or locally produced'.[77] This prohibition on discrimination as regards 'the field of technology' means that South Africa cannot single out inventions in the health sphere – as the IP policy seeks to do – and subject them to stricter patentability criteria. Such an approach, as the WTO's Dispute Settlement Body (DSB) has confirmed, is barred by the non-discrimination clauses in Article 27.1.

The dispute here arose between Canada and the European Union (EU), for the EU objected to Canadian patent rules allowing early regulatory review and the stockpiling of pharmaceuticals still under patent protection. When the matter came before it, the WSB rejected the stockpiling rule. However, it upheld Canada's system of early regulatory review (the Bolar exception), which allowed generic manufacturers to obtain regulatory approval for their copied medicines before the relevant patents had expired. In handing down its ruling, the WSB expressly pointed out that 'two of the primary purposes of Article 27.1 were to eliminate two types of discrimination that had been practised against pharmaceuticals (and certain other products) – either a denial of patentability for such products or, if patents were granted, automatic compulsory licences permitting others to manufacture such products for a fee.' As this ruling confirms, Article 27.1 of TRIPS does not allow member states to introduce stricter patentability criteria for pharmaceuticals, as the IP policy document incorrectly suggests.[78]

The IP policy also suggests that Article 27.1 must be read together with other TRIPS provisions (notably, Articles 1, 7, and 8) – and that these provisions, when considered in combination, do indeed allow South Africa to use different criteria for patentability where it is seeking to address its 'public health concerns'.[79] Again, however, the IP policy (like the 2016 IP framework which preceded it) is misleading as to what TRIPs requires and allows.

Article 1 of TRIPS states that 'members shall give effect' to its provisions. This wording is peremptory, not permissive. It also says that members are free to 'implement in their law more extensive protection than is required by this Agreement, provided that such protection does not undermine the provisions of this Agreement'. Hence, though members are free 'to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice', this does not mean that they can overlook or undermine the obligations they have agreed to fulfil.[80]

Article 7 states that 'the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge'.[81] This provision does not entitle South Africa to undermine innovation or ignore the interests of pharmaceutical companies (or other 'producers of technological knowledge') by narrowing the normal patentability criteria, as the IP policy suggests. There is also no justification for South Africa to do so when the Patents Act already provides that 'patents of addition' expire at the same time as the original patent – and so cannot be used to 'ever-green' patent rights, contrary to activist claims.

Article 8 is also far more limited than the IP policy suggests. It says that 'members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health,…provided that such measures are consistent with the provisions of this Agreement'.[82] Hence, though South Africa may 'adopt measures necessary to protect public health', it must also uphold its TRIPs obligations in doing so. Again, moreover, there is no 'need' to narrow the normal criteria for patentability when 'patents of addition' already prevent the supposed ever-greening problem.

The IP policy also claims that other countries, particularly Australia, have already 'raised the bar' by 'upwardly adjusting standards for patentability' and are now planning to 'make further changes to the inventiveness test'. Again, however, this is misleading. A High Court judgment in Australia dating back to 1977 had effectively set the test for an inventive step too low by saying that what was required, to show an advance on the prior art, was merely 'a scintilla of invention'. The changes recently introduced in Australia have thus sought to make the test more rigorous in various ways: for example, by saying that the skilled person against whose background knowledge the prior art is to be assessed should no longer be 'assumed to reside in Australia'. In addition, the further change that has now been recommended simply reaffirms the generally accepted criteria, for it says that an invention will 'be taken to involve an inventive step if, having regard to the prior art base, it is not obvious to a person skilled in the relevant art'. This is not a departure from the patentability criteria contained in TRIPS, but rather a confirmation of what those criteria require.[83]

What the IP policy implicitly seeks – though it shies away from saying so outright – is to amend the Patent Act so as to exclude from patentability any incremental pharmaceutical invention, such as a new use for an existing molecule or a new combination of existing molecules. This is what India has done in Section 3(d) of its 2005 patent law, which states (among other things) that the 'mere discovery' of a 'new use for a known substance' or 'a new form of a known substance' is not a patentable invention. This wording was inserted into Indian law to minimise the grant of 'secondary' patents and open the way for the generic substitution of 'primary' patents at an earlier time.[84]

However, it is doubtful whether India's rule against the granting of patents for secondary pharmaceutical inventions is consistent with TRIPS. As earlier noted, TRIPS is imperative in stating that 'patents shall be available' for all inventions which meet the core tests of novelty and utility. Hence, if an incremental invention does in fact make a significant advance on the prior art and meets the other core tests set out in TRIPS, it cannot be barred from patentability.

Whether Section 3(d) has had much impact, or is necessary at all, is also interesting to consider. The recent Sampat and Shadlen study examines the granting or refusal of secondary patents in India and various other countries over a specified period, and finds that Section 3(d) has seldom been cited as the sole reason for refusing a secondary patent. This analysis focused on some 5 000 pharmaceutical patent applications which had been made in these countries in the specified time and which had included a PCT filing. The study then

narrowed this sample down to applications for 'secondary' patents by excluding those which did not claim the discovery of a novel active ingredient.[85]

In seeking to assess the impact of Section 3(d) in India, the study focused on some 1 250 secondary PCT applications with Indian filings. Of these, roughly 40% had been granted, while some 30% had been withdrawn before examination and could not have been affected by Section 3(d). The authors continue: 'Of the 338 applications that were rejected, the vast majority (242/338) were rejected without any mention of 3(d), typically on conventional patentability grounds (novelty, inventive step, etc). Only 98 of the applications (8 per cent of the total) included any 3(d) rejection. However, most of these were also rejections on other (more conventional) patentability grounds. Only four applications were rejected on 3(d) grounds alone.'[86]

The Sampat and Shadlen study also found that grant rates in India for secondary patents were not much different from the country's grant rates for primary patents. The difference between primary and secondary grant rates was in fact much greater in the US, Japan, and the EU. These jurisdictions have no explicit restrictions on the granting of secondary patents, but nevertheless often reject secondary patent applications on the basis that the relevant inventions do not meet the standard tests for novelty. Contrary to expectation, the difference between grant rates for primary and secondary patents was in fact highest in the US, where the differential was 24 percentage points. In India, by contrast, 'grant rates for secondary patents were actually slightly higher than for primary patents, [though] the difference was small'.[87]

These findings cast doubt on India's key reason for including Section 3(d), which was to avoid the supposedly 'lax patent standards applied in developed countries'. The study also shows that secondary patents are generally more difficult to obtain, 'even using conventional patentability criteria'. The reason is not hard to find, for 'by definition, they are less likely to be novel or inventive than primary patents'.[88]

The IP policy cites a few figures from the Sampat and Shadlen study, but entirely ignores these key aspects of their analysis. Yet the study is important in showing that South Africa has little to gain from introducing into its Patents Act a provision modelled on India's Section 3(d). In many instances, the core patentability criteria – which are already contained in the South African Patents Act – will inhibit a secondary patent from being granted here. In addition, where the core patentability criteria for a secondary patent are indeed met, then the secondary patent must be granted if South Africa is to comply with its TRIPS obligations.

Ipasa's 2016 submission makes further important points. It starts by reaffirming, as earlier noted, that 'a new patent on new uses, forms, and combinations does not extend the duration of the original patent', contrary to what activists constantly assert. In addition, says Ipasa, 'even incremental innovations are valuable to patients,…as they provide improved treatment options…and result in improved health outcomes'. It urges that 'all inventions, whether further medical uses of known substances, new formulations, or new forms of previously known substances, and whether pioneering or incremental in nature, should be

evaluated….on their merits, according to properly and uniformly applied principles of patentability based on novelty, inventive step, and utility'. If this approach is applied, 'it is unnecessary to resort to arbitrary exceptions to patentability, which only serve to discriminate and deny protection to legitimate innovation'.[89]

Ipasa would like this evaluation to be provided through 'an effective SSE system'. However, such a system will be difficult to achieve in the light of South Africa's acute skills shortage and general governmental inefficiency. Until these factors have been overcome, South Africa should avoid introducing an examination system. This will not leave it defenceless against the continual ever-greening of pharmaceutical patents, as the IP policy implies. On the contrary, patents of addition do not extend the term of the initial patent, while any patent of addition which has wrongly been granted under the depository system can always be set aside by the patents court. The problems that the IP policy highlights are illusory – and there is thus no pressing need to amend the current patents system to tackle them. In addition, the Patents Act cannot be amended to tighten up the patentability criteria for pharmaceuticals without putting South Africa in breach of Article 27.1 of TRIPS.

Disclosure Requirements (Para 7.1.5)

As the IP policy acknowledges, South Africa's Patents Act already 'requires the applicant for a patent to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art'. This requirement is intrinsic to the basic bargain underpinning patent rights, and is thus already included in our legislation. Accordingly, there is no need for this provision in the 1978 Act to be changed, as the IP policy confirms.

The IP policy also proposes, however, that an applicant for a patent should also be obliged to 'provide information concerning the applicant's corresponding foreign applications and grants'. This proposal is in keeping with Article 29.2 of TRIPS. However, the proposal also assumes that South Africa will indeed be shifting to a full examination system, when its capacity to do so is far from clear. Whether the CIPC will be able to cope with the burden of evaluating disclosures from a host of other jurisdictions is also uncertain.

Parallel Importation (Para 7.1.6)

The IP policy states that Article 6 of the TRIPS Agreement 'gives members the flexibility to determine their own regimes for the exhaustion of IP rights'. Again, however, this distorts what TRIPS provides. What Article 6 in fact says is that, *'for the purposes of dispute settlement'* (and provided that member states do not discriminate against non-nationals), 'nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights'.[90]

Conflicting views over the exhaustion of patent rights (as further described below) proved so contentious when TRIPS was being negotiated that no substantive agreement could be reached. Hence, the Agreement simply provides that the normal dispute settlement mechanism provided by the WTO will not generally be available to deal with complaints

regarding exhaustion. In the words of Christopher Heath, of the Max Planck Institute for Foreign and International Patent, Copyright, and Competition Law, what 'this certainly means [is] that no country can be put in the dock for deciding for or against international exhaustion'. However, 'it does not necessarily mean that the TRIPS Agreement as such would favour either one or other position' on the issue of exhaustion.[91]

The exhaustion of patent rights is a complex issue. It is generally agreed that, once a patent holder has sold a patented product in the country where he has a patent, he has enjoyed the commercial benefit of his patent and cannot try to benefit again if the product is later re-sold. This is known as the 'national' exhaustion of patent rights and the law here is well settled. More difficult is the question whether a patent holder who has sold a product within a particular region has thereby exhausted his patent rights within the entire region. Particularly controversial is the concept of international exhaustion: the idea that a patent right is exhausted once the product is sold by the patent holder anywhere in the world. If that is indeed the position, then the patent holder cannot object to the product being imported, through a process of parallel importation, outside the distribution channels which he has established or approved.[92]

Views and practices on international exhaustion vary widely, but it is also generally agreed, as Mr Heath writes, that 'national patent rights [cannot be] rendered worthless by permitting parallel importation. Such might be the case if the patentee [the patent holder] could not object to the importation of products produced in third countries where no patent rights were obtained since, in theory and practice, this would require a patentee to apply for patents in all possible countries in order to receive at least once proper compensation for putting goods on the market… As yet, no country has permitted parallel imports in these circumstances'. [93]

The issue is thus complex and Article 6 provides no clear answer as to what is allowed. Instead, it simply states that the usual dispute mechanisms under TRIPS are not available to deal with disagreements over the extent to which a patent has been exhausted. Also relevant, however, is Article 28, which expressly states that a patent over a product gives its owner 'the exclusive rights…to prevent third parties not having the owner's consent from…making,…selling, or *importing'* that product. (The footnote to Article 28 to which the IP policy refers does not change the content of the owner's exclusive rights: it simply reaffirms that the normal dispute resolution mechanisms are not available for conflicts over the importing of patented products.)[94]

In the health context in South Africa, the crisp question is whether a pharmaceutical company holding a South African patent over a particular medicine can prevent the parallel importation of this patented product from another country where its price, for a wide variety of reasons, might be lower. Article 28 indicates that he may indeed prevent such importation. In addition, Section 45(2) of South Africa's Patent Act echoes this Article in stating that the patent holder has an exclusive right to import the patented product and can thus prevent others from doing so without his consent.

Notwithstanding these legal constraints, the Medicines and Related Substances Act of 1965 has been amended to allow parallel importation, but only where this will increase the affordability of medicines.[95] There is nevertheless, as the IP policy puts it, a risk that Section 45(2) of the Patents Act could 'give rise to challenges should parallel importation be pursued'.[96]

According to the IP policy, 'there is a need to clarify that parallel importation of medicines in the manner described in the Medicines Act does not constitute an infringement of the Patents Act'.[97] However, if the Patent Act were to be amended to allow parallel importation, this would prima facie be contrary to Article 28.1 of TRIPS. Under Article 6, other member states would not be able to invoke the normal dispute settlement mechanisms against South Africa – but this does not mean that the country would escape scot-free for this infraction of the TRIPS requirement.

Other adverse consequences would also follow. As Ipasa warned in its 2016 submission, 'parallel importation of pharmaceutical products into South Africa could pose significant risks to patients. International experience demonstrates that parallel importation encourages and facilitates the sale of counterfeit, sub-standard, or uncontrolled pharmaceuticals. It is extremely difficult to police the supply of medicines once the chain of supply from manufacturer to authorised importer is broken. Without that link, counterfeit and/or poor quality goods enter the drug supply more easily. Patients often cannot distinguish counterfeit or sub-standard pharmaceutical products. In the case of product withdrawal or recall, the manufacturer may not be able to identify parallel importers and alert them to recall decisions'.[98]

Adds Ipasa: 'Whilst parallel imports may seem like an attractive short-term solution, it will most likely lead, in the long-term, to less local innovation, more compliance and enforcement challenges, and their associated costs. We therefore caution against any effort to incorporate total international exhaustion into the Patents Act if the sole intent is to weaken patent protection.'[99]

If the cost of medicines is the key issue, then this problem can be addressed in other ways. Medicine prices are already strictly regulated in South Africa under the mechanism of the 'single exit price' (SEP). In addition, the single exit price cannot be increased – irrespective of how the diminished value of the rand has added to the costs of imported medicines or their active pharmaceutical ingredients – without the consent of the health minister. The price increases allowed by successive ministers have also generally been too limited to compensate adequately for inflation and the deterioration in the value of the rand.

At the same time, the single exit price bars pharmaceutical companies from offering discounts for bulk orders. This means that the government's own regulations are helping to keep medicine prices in the private sector higher than they might otherwise be. In practice, moreover, prices for medicines in the public health care sector are already very much lower (often by as much as 90%) than the prices of the same medicines in the private sector. High

prices in the private sector thus help to subsidise the low prices in the public sphere. This differential pricing greatly helps the poor, and must also be taken into account.

In addition, medicine prices in South Africa could be reduced by 14%, at the stroke of the government's own regulatory pen, if it was willing to exempt medicines from Value-Added Tax (VAT).[100] Various administered prices – including high electricity and port tariffs, for example – also contribute to high medicine costs in South Africa. Yet these prices are under the government's control and could be brought down with the necessary reforms and political will.

Overall, thus, there are many steps which the government could take to hold down medicine prices without abrogating patent rights. At the same time, pharmaceutical companies have themselves often helped to improve access to medicines for the poor by sharply reducing the prices of key medications for HIV/AIDS and other diseases.

Exceptions (Para 7.1.7)

The IP policy notes that the TRIPS Agreement 'allows members to provide limited exceptions to patent rights'. Article 30 of TRIPS does indeed allow 'limited exceptions' to the exclusive rights conferred by a patent. However, it also says that such exceptions must not 'unreasonably conflict with the normal exploitation' of a patent or 'unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties'.[101]

In the Canada and EU pharmaceutical patent dispute, the WTO's Dispute Settlement Body elaborated on the meaning of this Article. It also stressed that the non-discrimination obligation in Article 27.1 applies to the exceptions allowed under both Article 30 and Article 31. This indicates that pharmaceutical patents cannot be singled out for adverse treatment, with the rights of patent holders in this sphere made subject to limitations that do not apply in other fields of technology.[102]

Bolar exception, para 7.1.7.1

The IP policy is generally vague as to what exceptions to patent rights it seeks. It does, however, refer to the early regulatory approval or 'Bolar' exception that has already been incorporated into the Patents Act via a 2002 amendment. In the words of the IP policy, this provision allows 'generic producers to research, create, and test a patented product before the end of the term of the patent, thereby allowing its entry into the market as soon as possible once the patentee's exclusive rights lapse'.[103]

In the EU/Canada case, the Dispute Settlement Body (DSB) upheld a similar provision in Canadian patent law. It did so partly on the basis that, if generic manufacturers had to wait for patents to expire before they could begin the process of obtaining regulatory approval for their copied products, then this (given long delays in the regulatory process in Canada) could in practice add six or so years to the periods in which the patent holders would effectively still enjoy exclusive rights. However, the DSB also noted that patent holders were often

prejudiced by the same regulatory delays in obtaining approval for their original medicines. These long delays often greatly limited the periods in which patented products could be commercially produced and sold. The EU, Switzerland, the US, Japan, Australia and Israel thus allowed 'de jure extensions of the patent term, primarily in the case of pharmaceutical products, to compensate for the de facto diminution of the normal period of market exclusivity due to delays in obtaining marketing approval'. Other countries, however, had introduced Bolar exceptions without allowing compensatory 'extensions of the patent term for producers adversely affected by delayed marketing approval'. In these circumstances, the DSB declined to rule that a Bolar exception must be balanced by an extension of the patent term for the patent holder, saying 'the issue…was of relatively recent standing and the community of governments was obviously still divided over the merits of such claims'. [104]

Since then, however, as Ipasa's 2016 submission points out, international best practice has evolved further and is now reflected, for example, in the Hatch-Waxman Act in the US and in Directive 2004/27.EC in the EU. Writes Ipasa: 'The US Hatch-Waxman Act strikes a sensitive balance by allowing generics to conduct clinical trials during patent life for use in an abbreviated approval process,…while also allowing the innovator to extend the patent life to (a) fully compensate for the time lost during the non-abbreviated, ie innovative approval process, and (b) for half the time it took to conduct its innovative clinical programme in support of the first approval. However, the innovator can never obtain more than 14 years of effective exclusivity after approval of the product – despite the delays the innovator has been subjected to – in order to avoid the creation of very long exclusivity periods for pharmaceuticals.'[105]

The EU Directive is similar, says Ipasa, for it establishes a special IP right (a Supplementary Protection Certificate or SPC) that 'can be obtained solely in relation to patents that were subjected to regulatory delays in the clinical testing and regulatory approval periods in the pharmaceutical sector'. The duration of an SPC depends on a complex formula. In essence, it compensates for up to five years of delay suffered, but can never provide an exclusivity term of more than 15 years after approval.[106]

In order to strike a more reasonable balance between the interests of innovator companies and those of generic manufacturers, South Africa's existing Bolar provision should be modified to include wording similar to that in the Hatch-Waxman Act and the EU directive. This is important here, for the Medicines Control Council (MCC) – which was replaced as from 1st June 2017 by the South African Health Products Regulatory Authority (the Authority)[107]– is notoriously slow in processing applications for the registration of both innovative medicines and generics.

In May 2017, according to the council's registrar, Joey Gouws, there were some 7 900 products awaiting registration by the MCC, with some of these applications dating back to 2012. Of these 7 900 products, 3 500 were under review and some 4 400 were still waiting to be allocated to evaluators. The MCC has introduced a fast-track process for medicines that

are urgently required and this is supposed to take a maximum of nine months. In practice, however, it often takes double that time.[108]

The MCC's approval times, outside the fast-track process, generally average three years for generics and five years for innovative products. (However, one medicine – the only treatment for a rare disease – has still to be registered after seven years.) The new Authority is supposed to have more capacity than the MCC. But it will also have a much broader mandate, for it will oversee a wider range of medical devices and a huge number of complementary medicines, among other things. It will also be expected to 'ensure the periodic re-evaluation or re-assessment and monitoring of medicines, medical devices, and in vitro devices'. This in itself is likely to prove an enormous task.[109]

Long delays in the registration of both innovative and generic pharmaceuticals are thus likely to continue, notwithstanding the MCC's replacement by the Authority. This provides all the more reason for South Africa to introduce its own version of the US Hatch-Waxman Act and EU directive.

Research and experimental use (para7.1.7.2)

The IP policy urges that a 'research exception' to patent rights should 'extend beyond the health sphere' and allow 'the use of exceptions for research and experimental activities' in various other (unspecified) spheres. Without more information as to what it is envisaged, it is difficult to comment on the proposed changes. However, the Patents Act already includes a research exception, for which provision is often made in patent law. It is thus unclear why further unspecified amendments should be needed.

Voluntary Licences (Para 7.1.8)

Patent holders often grant individuals or firms voluntary licences to exploit their patents. Such agreements allow licensees to make, import, or sell patented products in return for the payment of agreed royalties to the patent holder.

The IP policy acknowledges that voluntary licensing in South Africa has already contributed to 'generic competition, lower prices, and [increased] accessibility, particularly where antiretroviral drugs (ARVs) used in the treatment of HIV/AIDS are concerned'. But the document also glosses over the positive impact of these agreements, instead suggesting that voluntary licences are flawed because their terms – on issues such as the number of licensees and their geographical spread – often differ.[110]

Yet negotiations and voluntary licences (sometimes concluded with the help of international organisations such as the Clinton Health Access Initiative or CHAI) have already helped achieve 'the world's lowest HIV drug prices', as *Business Day* reported in August 2017. 'Three-in-one' ARVs, containing Dolutegravir, Tenofovir, and Lamivudine, are also shortly to be made available to the public health care sector in South Africa (and some 90 other low- and middle-income countries) under a voluntary licence granted by the patent holder to

generic manufacturers. This agreement was brokered with the help of the CHAI and the Bill & Melinda Gates Foundation in order to increase the availability of new fixed-dose combination therapies.[111]

In South Africa these three-in-one pills, which need be taken only once a day, are intended to be used as first-line treatment. Clinically, these pills have fewer side-effects, so their use will help limit the development of resistance to ARVs (a problem which currently affects some 10% of those on treatment.) The reduced price that has been agreed will also substantially reduce HIV treatment costs. Comments health minister Dr Aaron Motsoaledi: 'This is a major breakthrough for South Africa, as it means we're going to reach 6 million people (with HIV) over the next six years and save R6 billion.' (South Africa has some 7.1 m people living with HIV, of whom just over 4m are on treatment.) According to Treatment Action Campaign spokeswoman Lotti Rutter, 'it is impressive that the entire three-drug regimen will be available for a maximum of $75 a year, as currently a month's supply of the originator version of Dolutegravir alone costs almost that much in South Africa'.[112]

The voluntary licence here in issue has been granted by ViiV Healthcare. As Ipasa points out in its 2016 submission, ViiV Healthcare is the HIV joint venture created by three pharmaceutical companies, GlaxoSmithKline, Pfizer, and Shionogi. Adds Ipasa: 'This venture grants royalty free voluntary licences on all of their current medicines (including those in their pipeline, once authorised for use) for public sector and donor agency programmes in all low-income countries, least-developed countries, and all of sub-Saharan Africa. ViiV Healthcare has given 16 voluntary licences for their ARVs to generic manufacturers, [and] does not charge royalties in [any of] these countries. Some middle-income countries are also covered by ViiV licences, on which royalties may apply. In total, 138 countries are covered.'[113]

Pharmaceutical companies have also agreed to reduce the prices of other medicines needed in South Africa. In March 2017, for example, Otsuka Pharmaceutical, a Japanese company, agreed to make Delamanid, a new drug for the treatment of tuberculosis, available for free to the Department of Health for the use of 400 people. Its cost is currently R40 000 per patient.[114] Swiss pharmaceutical company Roche has also lowered the price of its breast cancer drug Trastuzumab to state patients in South Africa. The drug is now being provided at a limited number of hospitals, but Roche is already in talks with the government to make it more widely available.[115]

In addition, many Ipasa members participate in the Medicine Patents Pool (MPP), which relies exclusively on voluntary licensing arrangements. Says Ipasa: 'Many support other programmes designed to promote access to medicines and accelerate discovery of treatments that address urgent global health challenges', including the Drugs for Neglected Diseases Initiative. Many pharmaceutical companies also use differential pricing, which 'enables [them] to offer significantly discounted prices for innovative medicines to lower-and middle-income patients within a country who would otherwise face significant affordability barriers. At the same time, manufacturers are allowed to maintain value-based market pricing for

upper-income patients who either have insurance coverage or can afford to pay out of pocket.'[116] Ipasa adds:

> If effectively implemented in partnership with the South African government, this framework could help achieve two linked policy goals that are critical for an emerging economy like South Africa: (i) significantly expand patient access to innovative medicines, and (ii) preserve the South African market as an attractive destination for pharmaceutical R&D investment and new drug launches.
>
> For example, Pfizer, together with the Bill & Melinda Gates Foundation and several large American and European innovative manufacturers, is partnering with the governments of Ghana and the Philippines to pilot the implementation of differential pricing policies. In 2015-16, the partners will offer differentially discounted prices to identified patient population segments that currently face major affordability barriers. The pilots are providing the partners the opportunity to learn about implementation challenges and to measure the impact on patient access to medicines. This model can also be replicated in South Africa.

Voluntary licensing and other price agreements by pharmaceutical companies have thus been highly effective in lowering costs and increasing access to medicines. Contrary to what the IP policy suggests, there is thus little reason for South Africa to curtail the patent rights of pharmaceutical companies by insisting on compulsory licensing in wide-ranging circumstances. In addition, recent research by Canadian and US researchers has shown that compulsory licensing may be less effective than voluntary agreement in improving access to medicines,[117] as further described below.

Compulsory Licences (Para 7.1.9)

The IP policy claims that voluntary licences 'have not always provided the requisite level of access in disease areas other than HIV/AIDS and, to a lesser extent, Hepatitis C'. It thus asserts that 'South Africa requires a broader set of policy options to address instances where voluntary mechanisms prove insufficient or inadequate'. However, it gives no further information regarding these claims, making it difficult to evaluate their validity. This is a major shortcoming, especially as many of the other claims contained in the IP policy are not in fact substantiated by the sources it cites. In addition, the IP policy again overlooks relevant TRIPS requirements, along with many other important considerations.

This section of the IP policy begins by stating that South Africa '*will require* the scope compulsory licences to be strengthened and clarified'.[118] This suggests that the DTI has already made up its mind on the issue and has little interest in information and analysis showing the weaknesses in this preferred approach. The IP policy also states that the changes it proposes will 'be fair and compliant' with both international obligations and national law, but these claims are difficult to evaluate when the IP policy provides so little insight into what it envisages.

As the 2017 document suggests, the DTI's key objective is to make much greater use of compulsory licences. Compulsory licences are different from voluntary ones because, as their name suggests, they give licensees the right to exploit patented products without the consent of the patent holder. Compulsory licences thus erode patent protections against the inventor's will.

South Africa's Patents Act already allows the issuing of compulsory licences, but solely to counter the 'abuse' of patent rights, as further described below. These licences must also be granted by the patents commissioner, who also decides on the royalties payable. Relevant factors in this determination (according to the Patents Act) are 'the research and development' (R&D) undertaken by the patent holder, as well as the terms and conditions 'usually stipulated' in voluntary licence agreements. The IP policy sees these provisions as too limiting, and seeks to make compulsory licences both easier and cheaper to obtain.

The IP policy acknowledges that 'the TRIPS Agreement sets specific conditions for the use of compulsory licences'. However, it makes no attempt to set out what these conditions are. Instead, it simply refers to the Doha Declaration on TRIPS and public health, stressing that this gives member states 'the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'. As this wording shows, the Doha Declaration simply confirms that compulsory licences – which patent law both in South Africa and elsewhere has always permitted to counter the abuse of patent rights – may now also be granted where increased access to medicines is needed to counter conditions of 'national emergency or extreme urgency'.[119]

Contrary to what the IP policy suggests, the Doha wording does not give member states the freedom to decide for themselves *the terms* on which compulsory licences are to be granted in the health context. The Declaration confirms that TRIPS flexibilities may be 'used to the full'[120] in countering health needs of 'extreme urgency', but it does not say that members may go beyond these flexibilities. In addition, though the Declaration reflects international concern about the need to increase access to medicines in circumstances of this kind, it further stresses that 'intellectual property protection is important for the development of new medicines'. This balanced approach is also consistent with the wider Doha Ministerial Declaration of 20th November 2001, which speaks of the need to 'promote both access to existing medicines and research and development into new medicines'.[121]

What Article 30 of TRIPS provides is thus very important. This Article does indeed allow 'limited exceptions' to the exclusive rights conferred by a patent. However, it also says that such exceptions must not 'unreasonably conflict with the normal exploitation' of a patent or 'unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties'.[122] These requirements are mandatory and cannot simply be overlooked.

Article 31 of TRIPS further requires that patent holders be paid 'adequate remuneration', taking into account 'the value of the authorisation'. It also says that compulsory licences may

be granted only if 'the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time'. (This requirement may, however, be waived in cases of 'public non-commercial use', see *Government use*, below.) Article 31 also lays down various further requirements, as further described in IP and Competition Law, below.[123]

The UNDP article nevertheless suggests various ways in which these binding requirements might be circumvented. It proposes the introduction of new rules stating that a compulsory licence *must* be issued if negotiations on a voluntary agreement have not succeeded within a set period (say, 60 days) and if the patent holder has rejected mooted royalty payments (set, say, at 3% of the price of the copied product.)

The UNDP article claims that this regulatory framework would be in keeping with TRIPS, but this overlooks the clear wording of Article 31. Among other things, such limited royalty payments would not offer the patent holder 'reasonable commercial terms'. Moreover, when TRIPS says that 'adequate remuneration' should reflect 'the value of the authorisation', this does not mean that royalties may be based on the price of the copied products. Rather, it means that royalties must take into account the full market value of the patent the compulsory licensee is being permitted to use.

The DTI's 2016 framework did not directly endorse the proposals in the UNDP article, perhaps because these are so clearly inconsistent with TRIPS. Instead, it called for 'the provision of guidelines that could assist parties to achieve timely conclusion of the voluntary licence negotiations that are mandatory in certain cases'. The IP policy is similar but even less forthcoming as to what it intends. It also refers to the need for 'guidelines to be introduced', but is silent as to what these guidelines might contain.[124] This suggests that the DTI has become more wary of overtly proposing changes which are clearly contrary to TRIPS, even though it still plans to proceed with much the same ideas.

Attempting to coerce patent holders into granting compulsory licences in the manner suggested in the UNDP document is clearly contrary to Articles 30 and 31 of TRIPS. Trying to peg royalty fees at some 4% of the price of copied products would also be a breach of TRIPS. In addition, unreasonable conduct of this kind would deter innovator companies from embarking on the lengthy and costly process of developing new medicines to treat disease. It would thus undermine the careful balance between access and innovation which the Doha Declarations seek to draw. At the same time, compulsory licensing cannot overcome other important barriers to access, including the often poor quality of delivery in South Africa's public health-care system.

Against this background, it is worth considering how effective compulsory licences have proved in practice in reducing medicine prices and improving access to treatment. As Ipasa's 2016 submission points out, a recent comprehensive study shows that the compulsory licensing of ARVs 'typically *does not result in lower prices* for medicines compared with international procurement programmes and other alternatives'.[125]

In this analysis, published in the peer-reviewed journal *Health Affairs* in 2015, Canadian and US researchers Read Beall, Randall Kuhn and Amir Attaran constructed a database of compulsory licensing activity for ARVs. They then compared the prices attained through compulsory licensing against those in the World Health Organisation's global price reporting mechanism and the price and quality reporting tool of the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The authors found that 'compulsory licence prices exceeded the median international procurement prices in 19 of the 30 case studies, often with a price gap of more than 25%'.[126]

(Opponents of this study have criticised its methodology, but nevertheless indirectly support its findings on comparative prices. Under Article 31 of TRIPs, products made under compulsory licence can generally be sold only within the domestic market, which may be small. By comparison, agreements brokered by the Global Fund, for instance, often cover a large number of developing countries. The size of this market provides economies of scale and makes it feasible for pharmaceutical companies to reduce drug prices substantially. These agreements have also been entered into without the threat of easy compulsory licensing, raising questions as to how much this spur to action is required.)[127]

As the Beall, Kuhn and Attaran study also shows, compulsory licensing cannot address a range of other practical problems. Writes Ipasa: 'For example, after India granted a compulsory licence to Natco to produce a generic version of Bayer's cancer drug Nexavar, the price for that generic version – $178 per month – remained inaccessible to two-thirds of the Indian population, who live on $60 a month. Bayer, on the other hand, has a comprehensive patient access programme aimed at reaching those patients who cannot afford the medicine at any price. The issuance of compulsory licences in India has thus done little to address India's access to medicines problem. When Brazil issued a compulsory licence for an antiretroviral treatment in 2007, it took the local manufacturer two years to launch production of a generic version. A study by two Indian academics [also] finds that compulsory licences issued across countries have had no impact on health outcomes.'[128]

The IP policy ignores these practical considerations. Instead, it seems determined to make widespread use of compulsory licences, despite what TRIPS says and regardless of the many other weaknesses in this approach. Though it says little about what it plans to do, it provides some more detail of its proposals in two related spheres: the issuing of compulsory licences for government use, and the extent to which medicines made under compulsory licence may be exported.

Compulsory licences for government use (para 7.1.9.1)

Though prior negotiation is generally needed before a compulsory licence can be issued, Article 31 of the TRIPS Agreement says that this requirement may be waived by a member state 'in cases of public non-commercial use'.[129] According to the IP policy, the current Patents Act goes beyond what Article 31 requires by obliging ministers of state to enter into

'prior negotiations' before a licence for government use can be issued. The IP policy also criticises the statute for 'imposing adversarial litigation proceedings in the event a patentee does not agree to the conditions attached to the licence in question'.[130]

This description of the Patents Act is again misleading. What the relevant provision (Section 4 of the Patents Act) in fact says is that 'a minister of state may use an invention for public purposes on such conditions as may be agreed upon with the patent holder, or in default of such agreement, on such conditions as are determined by the patents commissioner on application by the minister and after hearing the patent holder'.[131]

The criticisms of these provisions in the IP policy echo those earlier contained in the UNDP article. This document also condemned the need for 'potentially lengthy and expensive court proceedings', and recommended that South Africa take advantage of the Article 31 flexibility allowing the issuing of compulsory licences without prior negotiation 'in cases of public non-commercial use'.[132]

The UNDP article thus urged that the Patents Act be amended so as to allow the government to use any patented invention 'after a fixed period of unsuccessful voluntary negotiations' and 'subject to the determination of adequate royalties after the fact'. The DTI's 2013 draft policy document added that no compensation for expropriation would be payable to the patent holder in these circumstances, as the patent holder would still retain its patent. Said the 2013 document: 'The compulsory licence does not deprive [the patent holder of] ownership...rights over protected IP. It is just an exception to the exclusive right. This is the reason why it is not treated as direct expropriation.'[133]

The 2016 IP framework was less overt in explaining its proposals. Instead, it simply stated that the requirements in the Patents Act 'may cause unwarranted delays and should be reviewed'. The present IP policy is careful not to speak of uncompensated expropriation or to spell out exactly what the DTI envisages. It also acknowledges that 'any proposal for government use in South Africa must be line with procedural fairness requirements in South African law'.[134]

Procedural fairness is, of course, important. But so too is substantive fairness and the content of South Africa's obligations under TRIPS. Any compulsory licence, even one for public non-commercial use, must comply with Article 30 of TRIPS. It must thus be a 'limited exception' to the patent holder's exclusive rights, it must not 'unreasonably conflict with the normal exploitation of the patent', and it must not 'unreasonably prejudice the legitimate interests of the patent holder, taking account of the legitimate interests of third parties'.[135]

The IP policy also claims that 'the scope of government use may extend beyond public, non-commercial use'.[136] It thereby suggests that the Article 31 flexibility applies to governmental use of any kind. However, it makes no attempt to substantiate this view. It also ignores the distinction between public non-commercial and other governmental uses which the TRIPS Agreement plainly draws.

The TRIPS Agreement does not attempt to define 'public non-commercial use',[137] perhaps because it sees the clause as self-explanatory. It does, however, distinguish between this and other 'use by government', to which the normal rules regarding compulsory licences clearly apply.[138] The activist view, seemingly echoed in the IP policy, is that any governmental use will fit within 'public non-commercial use' – but this interpretation is unconvincing.

Moreover, if the aim behind the IP policy is to empower the government to acquire compulsory licences over ARVs and other medicines and then authorise their use by a state pharmaceutical company charged with manufacturing generic copies for sale both in South Africa and abroad, it is doubtful whether this would count as 'non-commercial' use. For patents outside the health sector, any claim of this kind would be even more difficult to sustain.

Compulsory licences for export (para 7.1.9.2)

The normal rule under Article 31 of the TRIPS Agreement is that products made under compulsory licence must be used 'predominantly for the supply of the domestic market'.[139] However, as the UNDP article has pointed out, if South Africa is to build up an extensive local pharmaceutical industry producing a number of affordable generic medicines, it is vital that it should be able to sell not only into the country's relatively small domestic market but also into foreign ones. As the article puts it: 'The lack of a [domestic-use] restriction could result in a significant drop in prices, as licensees could achieve economies of scale by manufacturing for both South African and foreign markets.' [140]

The UNDP article sees two ways of bypassing the normal TRIPS constraint on exports. It notes, first, that this constraint falls away where a patent holder has 'abused' his patent and then assumes that such abuse is a form of anti-competitive conduct. On this basis, it further assumes that the export restriction will fall away wherever anti-competitive conduct can be shown.

Second, the UNDP article argues that the usual constraint on exports can be circumvented to a significant extent under the 30 August Decision of the General Council of the WTO. The IP policy implicitly endorses this view. However, the 30 August Decision has a limited ambit and cannot easily be used to justify any large-scale exports of generic medicines made in South Africa under compulsory licences.

The 30 August Decision was adopted in 2003, under paragraph 6 of the Doha Declaration on TRIPS and Public Health. It seeks to make it easier for countries which lack their own manufacturing capacity to import generic medicines which have been produced under compulsory licence elsewhere. However, various conditions must be met before these imports are allowed. Importing countries must notify the TRIPS Council that they lack manufacturing capacity in the pharmaceutical sector, or face situations of national emergency or extreme urgency, or require particular products for public non-commercial use. They must also 'specify the names and expected quantities of the products needed'.[141]

Exporting countries may supply only the quantities needed, and must use special packaging or apply 'special colouring or shaping to the products themselves' to help prevent these medicines being diverted to other markets. They must also notify the TRIPS Council of the countries and the products they are supplying. In addition, if a country wants to export to more than one country, it must apply for separate compulsory licences for each separate order. Moreover, the TRIPS requirement of prior negotiations with the patent holder is not waived, and must be met in both the importing and the exporting countries.[142]

The limitations in the 30 August Decision are clearly intended to prevent the waiver from being abused. Developing countries have complained about the practical difficulties in meeting the conditions, which prompted further discussions on the issue by the TRIPS Council in 2010. As yet, however, the 30 August Decision remains in place. Since January 2017, moreover, its terms have been directly incorporated into the TRIPS Agreement, as two-thirds of member states have now endorsed them. The 2003 limitations on exports are thus binding and cannot simply be ignored.

The 30 August Decision also provides a broad export waiver for all countries which belong to a regional trade agreement, provided that half of its members are least developed nations. In these circumstances, a generic medicine produced under a compulsory licence in one country may be exported to all other members of the regional association which 'share the health problem in question'. This is particularly relevant to the 15 members of the Southern African Development Community (SADC), as eight of them (more than half) are recognised by the United Nations as 'least developed' nations.[143]

Under these provisions, as the UNDP article points out, South Africa could export generic ARVs manufactured here to all SADC members sharing the same health problems. All that South Africa need do to benefit from this general waiver is to amend the Patents Act to incorporate the 30 August Decision.[144] This argument is well-founded, but the SADC market is a relatively small one and would probably not be capable of sustaining the expanded pharmaceutical industry the DTI seeks.

To circumvent this problem, the UNDP article claims that South Africa is entitled to export generics beyond the SADC region irrespective of what 30 August Decision might say. However, it fails to explain the basis for this view, simply asserting that South Africa may 'choose' whether or not to operate within the 30 August constraints. The UNDP document also urges that the export 'procedure should not be made more cumbersome than necessary', saying: 'Thus, for instance, South Africa could set a fixed time after which voluntary negotiations are deemed to have been unsuccessful (say, 30 days), and waive the requirement of prior negotiations altogether where the importing country has issued its compulsory licence under a situation of emergency, extreme urgency, or for government use'.[145] On this basis, says the article, a generic ARV manufactured in South Africa under a compulsory licence could be exported to any country which either also confronts a severe HIV/AIDS

pandemic or has issued a compulsory licence allowing government use of the patented product in issue.

However, if South Africa were to follow these recommendations, it would clearly be in breach of the 30 August Decision and other aspects of the TRIPS Agreement. These treaties simply do not allow the untrammelled export of generic medicines produced under compulsory licence in South Africa in the way the UNDP article envisages.

Like the earlier IP framework, the current IP policy brushes over these issues, instead simply noting that South Africa has already 'ratified the Paragraph 6 system' or 30 August Decision. It is silent on whether it plans to try and push ahead with the proposals set out in the UNDP article. Instead, it merely states that the government is 'cognisant of the…limitations' in the exports that are allowed. It also speaks of 'engaging stakeholders to find ways of ensuring that implementation is simplified as much as possible'.

IP and Competition Law (Para 7.1.10)

The 2016 IP framework gave various important pointers as to how the DTI hoped to use competition law to widen the scope for compulsory licensing. It clearly envisaged that, in instances of anti-competitive conduct, compulsory licences could be granted without prior negotiation with patent holders – and without having to comply with the export restrictions in TRIPs and the 30 August Decision. The IP policy is more vague, simply stating that 'competition law and policy have, in the recent past, been applied to cases involving IP and the public interest'. Against this background, it says, 'a joint effort is recommended, along with the Competition Commission, to clarify the remit and scope of the intersection between competition law and IP'.[146]

Most of what the IP policy goes on to say is too vague to provide any real insight into the DTI's intentions. The document does, however, state: 'The TRIPS Agreement gives members the scope to use competition policy as an instrument to facilitate access to medicines. Article 8 on its own, and in particular, read through the interpretative lens of the Doha Declaration on TRIPS and Public Health, empowers WTO members to take measures aimed at restraining anti-competitive practices. Both competition law and patent law together can be used to implement competition-related TRIPS flexibilities and advance consumer welfare.'[147]

To understand what this vague wording is likely to mean, it is necessary to refer back to the 2016 IP framework and to examine more closely what the current Patents Act, the TRIPS Agreement, the Doha Declaration, and relevant principles of competition law in fact require.

The 2016 IP framework

According to the IP framework, Article 31(k) of TRIPS 'allows members to use compulsory licensing as a remedy to anti-competitive practices'. This Article also allows 'such licences to be issued without complying with a number of TRIPS conditions, most notably: prior negotiation with patent holders…and the requirement of being predominantly for domestic use'. The IP framework criticised the compulsory licensing provisions in South Africa's

Patents Act for 'not taking full advantage of TRIPS flexibilities'. It also claimed that 'the judicial process provided by the Patents Act is, in general, more cumbersome than required in TRIPS,…particularly [as regards] Article 31(k)'.[148]

The IP framework thus sought 'a more streamlined administrative process for the issuing of compulsory licences'. It also suggested that 'guidance be introduced as to which practices would be considered anti-competitive', saying this could be done either 'by way an amendment to the Patents Act' or through 'guidelines'.[149] (Guidelines would presumably be introduced via regulation, outside the ambit of the normal legislative process, and may thus be the option that the DTI prefers.)

To understand the significance of these proposals – which the current IP document still seems intent on pursuing – some background information on the Patents Act and the TRIPS Agreement is needed.

Compulsory licences under the Patents Act and the TRIPS Agreement

Section 56 of the Patents Act already empowers the patents commissioner to grant compulsory licences. However, this can be done solely to counter four types of 'abuse' by patent holders, these being:[150]

- failure adequately to 'work' (or exploit) an invention in South Africa within three years of a patent being granted, provided 'there is no satisfactory reason for such non-working';
- providing insufficient supply to meet demand on reasonable terms;
- refusing to grant a licence on reasonable terms, where this is 'prejudicing' the country's trade, industry, or agriculture and it is thus 'in the public interest that a licence be granted'; and
- charging excessive prices for imported products compared to the prices charged in other countries where the same products are manufactured.

The TRIPS Agreement also allows the granting of compulsory licences. However, it also makes it clear, under Article 30, that these must 'not unreasonably conflict with a normal exploitation of a patent'. In addition, they must 'not unreasonably prejudice the legitimate interests of the patent holder, taking account of the legitimate interests of third parties'.[151]

The TRIPS Agreement further protects patent rights by saying that, where a compulsory licence is granted (including for 'use by the government'), then a number of stipulated provisions 'shall be respected'. As earlier indicated, preliminary negotiations with the patent holder and adequate remuneration are both required. In addition:

- the scope and duration of the [compulsory licence] shall be limited to the purpose for which it was authorised;[152]
- the compulsory licence must be used 'predominantly for the supply of the domestic market';[153]
- the compulsory licence must be terminated once the circumstances that promoted it 'cease to exist';[154]

- 'the legal validity' of the decision to grant the licence 'shall be subject to judicial review or other independent review'; [155] and
- any decision regarding the remuneration provided to the patent holder must also 'be subject to judicial review or other independent review'.[156]

However, members are 'not obliged to apply' some of these conditions – those dealing with prior negotiation, the scope and duration of the authorised use, and predominantly domestic supply – if the compulsory licence is 'permitted to remedy a practice determined after judicial or administrative process to be anti-competitive'. In addition, 'the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases'.[157] These provisions have prompted health activists to take a particular interest in the meaning of 'anti-competitive' – and to try and extend this far beyond its normal ambit.

The meaning of 'anti-competitive' practices

Against this background, it is easier to assess what the current IP policy means when it says that 'the TRIPS Agreement gives members scope to use competition policy as an instrument to facilitate access to medicines'. Also important is the document's further claim that 'Article 8 on its own and, in particular, read through the interpretive lens of the Doha Declaration on TRIPS and Public Health, empowers WTO members to take measures aimed at restraining anti-competitive practices'.[158]

Here, however, the IP policy (like the 2016 framework, which it follows verbatim) distorts and misinterprets the relevant TRIPS provisions. Article 8 says that 'appropriate measures…may be needed to prevent the abuse of intellectual property rights by rights holders', but it also stresses that these measures must be 'consistent with the provisions of this Agreement'.[159] In addition, the 'abuse' of a patent right is different from an anti-competitive practice.

An abuse of patent rights, as the Patent Act indicates, typically arises where a patent holder fails to 'work' or exploit the patent for three years after its grant and without having a satisfactory reason for this failure, as described above.[160] This is not an 'anti-competitive' practice, as defined in competition law. The Doha Declaration on TRIPS and Public Health, to which the IP policy misleadingly refers, does not change this reality – especially as that Declaration seeks to promote both access to existing medicines and the development of new medicines through patent protection.

The 2016 IP framework claimed that Article 40 of the TRIPS Agreement gives members 'a large degree of discretion in defining prohibited anti-competitive practices'.[161] The current IP policy omits this claim, perhaps because it is difficult to substantiate. The same thinking nevertheless seems to underpin the 2017 document, which makes it important to understand what Article 40 of TRIPS in fact provides.

Article 40 has a limited ambit, for it deals with the 'control of anti-competitive practices in contractual licences'. It thus applies to voluntary licences and not to compulsory ones. Within

the context of these voluntary agreements, it allows member states to 'prevent or control' certain 'licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the market'. It gives examples of the clauses that might be barred, saying these could include conditions preventing the voluntary licensee from 'challenging the validity' of the patent in issue.[162]

Article 40 thus applies solely to voluntary licences and provides some examples of the contractual clauses that TRIPS might regard as problematic. It certainly does not suggest, as the IP framework indicated and the IP policy may still seek to assert, that countries are free to adopt their own definitions of anti-competitive conduct and then apply them in the very different context of compulsory licensing.

Health activists in South Africa have nevertheless long been seeking to extend the meaning of anti-competitive practices in ways that go far beyond what either TRIPS or established principles of competition law would allow.

The UNDP article urges that the Patents Act be amended to state that the 'abuses' of patent rights which the statute lists in Section 56 (see above) would automatically be identified as 'anti-competitive' practices. It also wants Section 56 tightened up in various ways, so as to expand the conduct that would be 'deemed' uncompetitive – and would thus warrant the granting of compulsory licences without prior negotiation or adequate remuneration. [163] However, such amendments would clearly be contrary to TRIPS. In addition, the 'deeming' clauses proposed overlook the emphasis in TRIPS on any 'abuse' of IP rights having to be 'determined' through judicial or administrative processes, rather than presumed.[164]

The IP policy avoids making any clear proposals, but what it says is fully in line with the damaging ideas in the UNDP article. Moreover, though the current policy document avoids any reference to the *Hazel Tau* case – which the IP framework clearly saw as helping to stretch the normal meaning of anti-competitive conduct – it remains important to set out the many weaknesses in that decision in case the DTI is still seeking to rely on it.

The* Hazel Tau *case

Analysis of the *Hazel Tau* case requires an understanding of key provisions in South Africa's Competition Act of 1998. The Competition Act aims, among other things, at 'providing consumers with competitive prices and product choices'. The statute also prohibits firms with 'market dominance' from 'charging an excessive price that harms consumers' or from refusing a competitor access to 'an essential facility' when it is economically feasible to provide this.

Under the Competition Act, 'market dominance' is deemed to exist wherever a business has a 35% share of the market and cannot disprove its market power. In addition, an 'essential facility' is defined as 'an infrastructure or resource that cannot reasonably be duplicated and without access to which competitors cannot reasonably provide [goods or services to] their customers'.

Under American anti-trust law, essential facilities include infrastructure such as railway bridges, local electricity transmission networks, and sports stadiums. This is also the usual meaning of the term. However, in the *Hazel Tau* case, the then competition commissioner, Menzi Simelane, re-interpreted the term in an extraordinarily different way.

The case began in 2002, when the Treatment Action Campaign (TAC) and other various other organisations lodged a complaint with the Competition Commission against GlaxoSmithKline and Boehringer Ingelheim. The complainants alleged that, even after allowing for reasonable profits, licensing costs, and R&D expenditure, these firms were charging excessive prices for some of their patented ARVs, which made it difficult for people living with HIV/AIDS to gain access to these medicines.[165]

In 2003 the commission ruled against both companies, saying they had 'abused their dominant position in their respective ARV markets'. It found that the companies had not only engaged in excessive pricing but had also denied competitors access to an 'essential facility'. According to Mr Simelane, this 'essential facility' was the patented formula for their AIDS drugs. This was an extraordinary and unwarranted decision. In response, an editorial in *Business Day* warned that this 'novel' interpretation of competition law would undermine patent protection in South Africa not only in the health sector, but also in all other spheres.[166]

Mr Simelane recommended that the matter be referred to the Competition Tribunal for a confirmation of his ruling. However, the companies avoided these further proceedings – and the additional one-sided and damaging publicity they were likely to generate – by seeking a voluntary settlement. Though they denied contravening the Competition Act and said their AIDS drug prices in South Africa were already among the lowest in the world, they also agreed to issue a total of seven voluntary licences to local firms to either produce or import relevant generics. The royalties payable were fixed at 5% of net sales of the generics. The two companies also granted these licensees permission to sell their generic copies not only in South Africa but also in all other countries in sub-Saharan Africa.[167]

Questions nevertheless remain as to whether Mr Simelane was correct in ruling that GlaxoSmithKline and Boehringer Ingelheim were engaged in 'excessive pricing' when their ARV prices were already among the lowest in the country. In addition, there are doubts as to whether the commissioner's 'novel' interpretation of an 'essential facility' is defensible in the light of competition decisions elsewhere.

Mr Simelane's finding on the 'essential facilities' doctrine contradicts relevant rulings in Europe, which caution that an overly broad approach in this sphere is likely to negate patent rights and undermine innovation. Writes James Turney, research fellow at the Centre of European Law and Politics at the University of Bremen:[168]

> Where the intellectual property owner has an objective justification for refusing to allow access to an essential facility, a compulsory licence should not be granted… If a

> licence to a right is granted in most circumstances where a competitor needs access to compete with the rights holder, the advantages associated with intellectual property protection become illusory… Any other interpretation of the essential facilities doctrine would undermine the very substance of an intellectual property right… A broader interpretation of essential facilities also ignores the need to compensate the right holder for the risk undertaken [by him]…. [Moreover,] it is one of the key aims of competition policy to increase innovation.

Given the pharmaceutical companies' decision to settle the dispute, the validity of Mr Simelane's ruling was never put to the test. Had the matter gone to adjudication before South Africa's Competition Tribunal, it is doubtful whether Mr Simelane's ruling would have been upheld. The TAC seems also to have acknowledged this in 2003, when it hailed the settlement reached as 'going well beyond what could conceivably have been won by pursuing the prosecution of the complaint under the Competition Act'.[169]

It is doubtful too if the outcomes of the *Hazel Tau* case would have survived critical scrutiny under the TRIPS dispute settlement mechanisms, had this occurred. For the TRIPS Agreement makes it clear that the 'limited exceptions' to patent rights that it allows must not 'unreasonably conflict with the normal exploitation of a patent', or 'unreasonably prejudice the legitimate interests of the patent holder'. Though TRIPS adds that 'the legitimate interests of third parties must also be taken into account', this last consideration does not outweigh the other two. Moreover, the patent holders here had already taken account of the 'legitimate interests of third parties' by significantly reducing their ARV prices. Despite this, they were penalised in ways that 'unreasonably conflicted' with their patent rights, 'unreasonably prejudiced' their legitimate concerns, and effectively made a mockery of the patent protection that TRIPS requires its member states to provide.

The 2016 IP framework versus the 2017 IP policy document

The IP framework ignored the fundamental weaknesses in the *Hazel Tau* decision. Instead, it hailed the case as 'a watershed', saying it showed how competition law could be used to strike what it (wrongly) described as 'an appropriate balance between the interests of the creators and users of IP'.[170]

The IP framework noted that 'few parties have sought to use the provisions of the Competition Act to alleviate the adverse impacts of [patent rights] on…public health'. It blamed this on the costs of litigation, 'the highly technical nature of the requisite analysis' and the fact that the South African market is too small for generic manufacturers to have much interest in pursuing this option. To overcome these obstacles, the IP framework proposed that 'guidelines on IP and competition could be developed'.[171]

The current IP policy, by contrast, avoids any overt endorsement of the *Hazel Tau* decision or clear explanation of the changes it seeks. The risk, however, is that the DTI, in conjunction with the competition authorities, will seek to build on Mr Simelane's flawed decision to expand the meaning of anti-competitive practices. However, this would be inconsistent with

the accepted meaning of the 'essential facilities' concept. Granting generic manufacturers compulsory licences whenever patent holders have refused to allow them the use of their patented formulas would also clearly be contrary to TRIPS.

Replacing the patents court with a patents tribunal (see para 7.1.9)
Under South Africa's Patents Act, compulsory licences may be granted only in limited circumstances. They must also be granted by the patents commissioner and then only after a comprehensive hearing in the patents court. The UNDP article castigates these requirements, saying they make for 'lengthy litigation during which the issuance of a compulsory licence will be delayed'.[172]

The IP policy echoes this approach. It criticises the fact that 'applications for compulsory licences in South Africa are subject to a judicial process before the Commissioner of Patents'. This, it says, makes the 'grant of a compulsory licence subject to the timeframes and expenses that apply to litigation'. Furthermore, it adds, 'this process can be exacerbated and access further delayed, in the event the decision of the Commission to grant a licence is appealed'.[173]

The 2016 IP framework contained precisely the same criticisms. It also went on to claim that 'the TRIPS Agreement does not require the grant of compulsory licences to be made subject to a judicial process'. It thus urged that 'a more streamlined and accessible administrative process should be considered'.[174] The 2017 document again shies away from spelling out what it seeks. However, its wording suggests that the DTI's objective remains essentially the same, for it stresses the need for 'a workable' system of compulsory licensing,[175] which it presumably wants to be shorn of 'the timeframes and expenses' arising from litigation.

The IP policy also echoes the UNDP article, which is again useful in providing an insight into what the DTI may intend. The UNDP document criticises the role of the patent court in adjudicating patent matters. It also castigates the normal rules of civil procedure, as applied in the patents court, saying these make for unnecessary complexities, costs, and delays. It thus recommends that these court proceedings should be replaced by a simplified process, in which decisions on compulsory licences would be made by an 'administrative tribunal'. Such decisions would have to remain subject to court review, as this is required by constitutional rights to administrative justice and access to court. However, the practical value of seeking judicial review could be limited by another new rule, under which the use of a compulsory licence granted by such an administrative tribunal could not be stayed (placed on hold) pending the finalisation of the review.[176]

The DTI's 2013 draft policy document overtly espoused a similar view, saying the 'enforcement of intellectual property is expensive and that judicial systems are under severe strain'. It thus proposed the establishment of a patents tribunal, which would operate outside South Africa's high court and would be responsible for hearing all patent matters. This new tribunal, it said, should not be 'dominated by lawyers' or subject to high court rules, as these make for 'highly technical and legalistic procedures'.[177]

The 2016 IP framework was less candid, but it nevertheless urged a shift from a judicial to an administrative process. It also claimed that that the TRIPS Agreement does not require the judicial proceedings for which the current Patent Act makes provision. However, in making this claim, the IP framework overlooked various binding TRIPS provisions.

Relevant first is Article 42 of TRIPS, which states: 'Members shall make available to rights holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement... Parties shall be allowed to be represented by independent legal counsel,...and all parties to such proceedings shall be duly entitled to substantiate their claims and to present relevant evidence.' Article 49 adds that, where 'any civil remedy is ordered as a result of administrative procedures on the merits of a case', these administrative procedures must 'conform to principles equivalent in substance' to those applicable in the civil courts. [178] These provisions are peremptory, and cannot simply be disregarded.

The IP framework did not elaborate on the further changes it saw as contributing to a 'more streamlined and accessible administrative process'. The current IP policy is even less clear about what it considers necessary for the 'workable compulsory licensing system' it seeks.[179] It may still be planning, thus, to restrict the role of the patents court in the ways outlined. It may also intend to limit the remedies available to patent holders, as both the UNDP article and the 2013 draft policy document expressly proposed.

These documents recommended that the remedies available to patent holders should be restricted by barring them, in many instances, from obtaining either interim or final interdicts (injunctions). Yet an interim interdict – to stop sales of copied products pending a court order confirming the alleged infringement – is often the most effective remedy available to the patent holder. In addition, refusing to grant a final interdict (after infringement has been established by the patents court) 'amounts to granting the infringer a compulsory licence', as Judge Louis Harms, a retired deputy president of the Supreme Court of Appeal, has noted. [180]

Should the DTI attempt to introduce these additional changes, this will further contravene the TRIPS Agreement, which requires member states to ensure 'effective action' against any infringement of intellectual property rights. TRIPS also stresses the need for 'remedies which constitute a deterrent to further infringements'. In addition, TRIPS provides that 'the judicial authorities [in a member state] shall have the authority to order prompt and effective provisional measures' and the capacity to 'order a party to desist from an infringement'. Again, these provisions are peremptory and cannot be ignored.[181]

The UNDP article also recommends that patent holders should be deterred from enforcing their rights by new rules that would entitle the defendants in infringement proceedings to counterclaim for compulsory licences in wide-ranging circumstances. However, any such changes would also be contrary to the overall TRIPS scheme for 'the enforcement of intellectual property rights'. It would also be in breach of a TRIPS provision stating that 'procedures' for the enforcement of intellectual property rights must be 'fair and

equitable'.[182] Penalising patent holders for trying to enforce their rights would hardly satisfy this requirement.

Ramifications of the IP policy

The IP policy, like the UNDP article, the DTI's 2013 draft policy document, and the 2016 IP framework assumes that the changes it proposes are in keeping with the TRIPS Agreement, the Doha Declarations, and the 30 August Decision of the WTO. However, this is not so, for all the reasons earlier set out.

The IP policy also assumes that many positive consequences will flow from its proposals: the allegedly common practice of 'ever-greening' patented medicines will fall away; a host of generics manufacturers (including a state pharmaceutical company) will spring up to produce cheap generic drugs for both domestic and export markets; the current 'de-industrialisation' of South Africa will be reversed; and poor people suffering from AIDS, drug-resistant TB, malaria, and other serious illnesses will have early and cheap access to the new and more effective medicines still to be developed in the United States, Europe, Japan, and elsewhere. However, abrogating patent rights in the way proposed is unlikely to improve health care or promote industrialisation – and could have many adverse consequences for the wider economy.

Ramifications in the health-care sector

Activists often exaggerate the extent of the patent 'problem' within the health-care sector and to assume that generic substitutes will always have the same therapeutic quality as original medicines. In addition, undermining patent rights will do little to overcome a host of other barriers to good public health care in South Africa. Moreover, there are different and more effective steps that could be taken to bring down the prices of patented medicines, improve the quality of public health care, limit the spread of HIV and drug-resistant TB, and make it easier for many more South Africans to buy high-quality health care from the private sector.

The extent of the patent 'problem'

Roughly 98% of the medicines needed to treat the majority of patients in South Africa – as set out on a list of essential medicines compiled by the World Health Organisation (WHO) – are already off patent. The TAC discounts this, saying that many of the medicines found on the WHO list have been included not only because of their 'efficacy' but also because of their 'comparative cost-effectiveness'. This means, it says, that many innovative medicines are left off because of their price, whereas 'if costs were no barrier, many additional medicines would be included'.[183] But costs are unavoidably important, while undermining patent rights to bring them down puts innovation at risk. Without secure patent rights, there is less incentive to explore and develop new drugs – and the pipeline of innovation on which generics manufacturers depend is likely to dry up. There are few benefits to anyone in this scenario.

It is also over-optimistic to presume that the generics to be produced under compulsory licence will have the same quality as original medicines. Moreover, if the active pharmaceutical ingredients are not in fact equivalent, this can have serious consequences.

'Inferior versions can be fatal to the patients and promote drug resistance,' warns a recent report by the National Bureau of Economic Research in the United States. The bureau's researchers tested some 1 470 products made by Indian generics manufacturers and sold in Africa, India, and elsewhere. They found, for example, that 17.5% of the TB therapy rifampicin sold in Africa tested sub-standard, as 'the drug had less than 80% of the active ingredient that it should'.[184]

Other evidence also indicates that the generics drug industry in India, in particular, is falling short on quality standards. A number of Indian pharmaceutical companies have recently had to recall various medicines from the US market. In June 2014, for instance, Sun Pharmaceutical Industries, one of the largest Indian generics companies, recalled close on 400 000 bottles of a decongestant and more than 250 000 of an antidepressant because the pills failed to dissolve properly, reducing the bioavailability of their active pharmaceutical ingredients.[185]

In the US, generic versions of a heart disease drug (Toprol XL) have had to be recalled at various times for the same reason – and this after thousands of patients had complained of increased blood pressure, nausea, headaches, and dizziness after switching from the branded product. Since 2012, Ranbaxy Laboratories, another major Indian generics manufacturer, has three times had to recall its generic versions of a cholesterol drug from the US market. The biggest of these events took place in 2012, when the company recalled close on 500 000 bottles because some of them were found to be contaminated with tiny glass particles.[186]

In January 2014 the Food and Drug Administration (FDA) barred the entry into the US of drug ingredients made at some Ranbaxy plants in India because of the alleged faking of test-quality results by plant workers. In 2013, moreover, Ranbaxy agreed to pay $500m in fines and to plead guilty to criminal charges of selling adulterated drugs and making false statements to the FDA. Overall, FDA has become so concerned about the quality of Indian drug manufacturers that it has barred 36 manufacturing plants, including facilities owned by Ranbaxy and Sun Pharmaceuticals, from sending their products to the US.[187]

If India's established generics industry fails to maintain adequate standards of quality, South Africa's proposed new state pharmaceutical company, Ketlaphela, is likely to face similar challenges in doing so. So too could other generics manufacturers battling to obtain a foothold in a highly competitive global market.

These considerations are not lightly to be discounted. Moreover, there is little reason to believe that undermining patents will help to improve public health care in South Africa when intellectual property rights are not the key reason for problems in this regard. Even if Ketlaphela and various other domestic manufacturers were to start producing high-quality generics at low prices under the DTI's proposed new rules, this would do little to improve the quality and availability of public health care in South Africa as all the other obstacles to sound health care would remain. These include poor management of public health care facilities; shortages of health care professionals; frequent medicine stock-outs; a failure to

maintain or repair essential infrastructure and machines; increasing instances of medical negligence; and persistent financial mismanagement in provincial health departments, in particular.[188]

Better solutions available

Rather than undermining patent rights, the key need is to improve efficiency and quality in the public health-care service, make better use of the tax revenues available, limit the spread of HIV and drug-resistant TB, allow pharmaceutical companies to provide discounts for bulk orders for medicines in the private sector, and increase access to private medical aid and health insurance. Where health needs nevertheless remain beyond the capacity of the government to address, it should not seek to transfer part of this burden to the private pharmaceutical industry but could rather request the help of international donors.

The immediate priority is for the government to put its own house in order. Much of the country's health budget (set at R186.6bn for public health care expenditure in 2017/18)[189] is badly used. South Africa allocates around 12% of budgeted government spending to public health care, amounting at present to some 3.9% of GDP. In nominal terms, the health budget has increased by more than 1 000% since 1994. However, South Africa gets far too little bang for its health care buck.

Where more money for medicines is required, the government could thus help meet this need by cutting back on its own corrupt and wasteful spending. How much the state loses each year to fraud and inflated pricing is difficult to tell. In 2016, however, Kenneth Brown (then the chief of procurement in the National Treasury) estimated that between 30% and 40% of the state's total annual procurement budget, amounting to some R600bn, is tainted by these problems. Between R180bn and R240bn in state expenditure every year is thus flawed in these ways.[190]

The government could also take more effective steps to reduce the number of new HIV infections, which in turn would reduce the demand for costly ARVs. In 2012, for instance, new HIV infections in South Africa numbered 400 000. This was seven times the number of new infections in the United States, which has six times the population, and made South Africa number one in the world in HIV incidence. In the words of the then leader of the Democratic Alliance, Helen Zille, the government needs to move away from its current focus on condoms, testing, and ARVs to tackle 'the underlying behaviour responsible for the rampant spread of the virus: multiple concurrent (or overlapping) sexual partners, and inter-generational sex'. Moreover, the success of the 'zero grazing' programme in Uganda – which focused on the need for fidelity between ordinary people in ordinary relationships and helped bring Uganda's infection rate down by two-thirds within a decade – shows how effective such initiatives could be.[191] However, no similar initiative has been taken in South Africa, where the number of new infections, at some half-a-million, remained very much the same in 2015.

As for TB and the drug-resistant varieties of the disease now on the rise, the Government needs to begin by ensuring the efficient operation of the country's 3 200 or so primary care clinics.[192] On this basis, it could implement much more comprehensive screening for TB. It could also be more effective in monitoring patients and ensuring their proper compliance with treatment protocols, so as to halt the rise of drug-resistant strains of the disease.

Medicine prices in the private sector could also be reduced in various ways, without interfering with patent rights. As earlier suggested, the government could remove VAT on all medicines sold in the private sector. It could allow pharmaceutical companies to offer discounts on medicine prices for bulk orders in the private sector, which is current barred by the single exit price mechanism. It could also promote the 'differential' pricing which Ipasa has proposed to bring down medicine prices for the poor, while retaining higher prices for those able to afford them. [193]

The government also has the power to shift the focus of its policies from redistributing the existing economic pie to growing it through rapid rates of economic growth. In addition, the state could take various steps to foster entrepreneurship and encourage job creation, thereby making it possible for millions more people to earn their own living and buy the health care they need.

In addition, the government could reduce the cost of medical aid membership by sanctioning a return to the risk-rating of premiums and allowing the low-cost options (at monthly premiums of some R180 per person) the Council for Medical Schemes has earlier proposed. It could also encourage individuals to obtain 'gap' medical insurance, hospital cash plans, and primary health care policies instead of trying to restrict or eliminate these options.

The state could also privatise floundering public hospitals and clinics and use the proceeds, along with a portion of tax revenues, to issue all households with annual health vouchers that would help them buy the medical aid membership and additional health insurance they require. In combination with measures to increase the supply of health practitioners and reduce the regulatory burden within the health sector, these initiatives would help to hold down medical inflation and raise the quality of health services within the country.

Where the health needs of the poor still cannot be met, the answer is not to undermine patent rights but rather to seek the help of international donors. In its fight against AIDS, South Africa has already benefited enormously from the President's Emergency Plan for AIDS Relief (Pepfar), which started in 2003 under President George W Bush. Since then, as *The New York Times* reports, 'Pepfar has poured more than $3bn into South Africa, largely for training doctors, building clinics and laboratories, and buying drugs'. Though the US contribution had passed largely unremarked within South Africa, it is Pepfar that has played the major part in expanding the number of AIDS treatment clinics (from 490 in 2008 to 3 500 in 2013) and in increasing the number of trained nurses (from 250 to 23 000 in the same period).[194]

Pepfar is now shifting its contributions to poorer nations and so reducing its assistance to South Africa. This means that roughly a million South Africans, whose ARVs were previously funded by Pepfar, must in future be treated out of the nation's own resources.[195] The reforms outlined above would help to achieve this. However, if South Africa nevertheless remains unable to manage the AIDS burden without outside help, it should seek this from international organisations, including CHAI, the Bill & Melinda Gates Foundation, and the Global Fund, rather than trying to shift the burden on to the shoulders of pharmaceutical companies.

Ramifications for industrialisation

Part of the DTI's purpose in seeking to abrogate patent rights is to foster the 're-industrialisation' of South Africa. It assumes the granting of many more compulsory licences over patented medicines will encourage the growth of a vibrant domestic pharmaceutical industry, including a state pharmaceutical company, which will be able to sell high-quality generics at low prices both locally and in export markets.

However, these assumptions are fundamentally flawed, as earlier noted. The government itself has done much to drive pharmaceutical manufacturing companies out of the country, while the state pharmaceutical company, Ketlaphela, is still battling to get off the ground. Pharmaceutical companies manufacturing medicines in South Africa also face a host of other obstacles, which range from high electricity, labour, and other input costs to poor skills and productivity and limited international competitiveness. The domestic market is also small, while South Africa cannot simply ignore TRIPS restrictions on the exporting of products made under compulsory licence. Abrogating patent rights will not solve these problems, and could accelerate the de-industrialisation of the country by driving investment away.

Constitutionality of the IP proposals and the proposed Intellectual Property Tribunal

WIPO's Policy Guide to Patent Examination indicates that countries with limited resources may introduce a patent examination process which is initially limited to particular spheres, such as the health sector, and in time expand this into other areas. However, South Africa, with its limited skills and rising levels of public debt, has little to gain from introducing an examination process in this way. Examination of medicines and other health products will also not bring the supposed 'gains' which the DTI seeks.

This is because the key change that a shift to examination is supposed to bring about – more onerous patentability criteria, particularly for secondary or incremental patents (along the lines of India's Section 3(b) – are contrary to the non-discrimination clauses in Article 27.1 of TRIPS and cannot lawfully be introduced. The DTI also wants to develop new administrative processes for pre- and post-grant opposition, presumably to be implemented via the Intellectual Property (IP) Tribunal being introduced under the Copyright Amendment Bill (see below). But Section 33 of South Africa's Constitution requires administration action to be 'reasonable' and 'lawful'. Administrative decisions which contradict South Africa's binding obligations under TRIPS are incapable of meeting these criteria and are prima facie unconstitutional.

The other key changes the IP policy seeks are also contrary to TRIPS. Among other things, TRIPS does not authorise parallel imports of patented medicines, which are prima facie contrary to Article 28 (even though the WTO's normal dispute settlement procedures cannot be invoked against such infractions, under Article 6). In addition, the granting of compulsory licences must comply with the conditions laid down in both Articles 30 and 31 of TRIPS, while the carefully balanced provisions of the Doha Declaration on TRIPS and Public Health do not change this reality. What the IP policy seeks, in the context of government use, compulsory licences for export, and compulsory licensing against anti-competitive conduct, is also contrary to TRIPS, for all the reasons earlier described. Moreover, the DTI's seeming determination to replace the patents court with the IP tribunal will also put South Africa in breach of various binding TRIPS provisions, also as earlier outlined.

Moreover, where the proposed IP tribunal makes administrative decisions in these various spheres – for example, in granting a compulsory licence without adequate prior negotiation or remuneration for the patent holder – these decisions will conflict, not only with TRIPS, but also with the guarantee of administrative justice in Section 33 of the Constitution, which requires all administrative action to be both 'reasonable' and 'lawful'.

The IP tribunal is vital to the DTI's plans to weaken and/or abrogate patent rights. However, it is unnecessary, unwise, contrary to TRIPS, and unconstitutional to replace the current Patents Court with this new body. At present, as earlier noted, the adjudication of patent disputes is entrusted to the commissioner of patents, who is both a specialist in intellectual property matters and a high court judge. This gives the patents commissioner the knowledge and experience needed to preside over the complex issues that disputes in the patents field commonly involve. It also means that the patents commissioner is likely to have high standards of individual independence and professional integrity, along with the security of tenure and wider institutional independence that all judges enjoy. In addition, the Patents Court applies the normal rules of evidence and civil procedure, the key purpose of which is to exclude unreliable evidence, uphold due process, and ensure that justice is not only done but is also seen to be done.

By contrast, the new IP tribunal will be a creature of the executive and, in particular, of the minister of trade and industry. All its members will be appointed by the minister, who will also have the power to decide their remuneration, extend the terms of office of those who please him, and suspend or dismiss those whom he thinks 'may' be undermining the integrity of the tribunal. No member of the tribunal will need expertise in intellectual property law. In addition, the majority of tribunal members could be public servants who belong to the ruling party or its communist ally and have little legal knowledge or capacity for impartial adjudication.[196]

In proceedings before this flawed IP tribunal, the usual rules of evidence and civil procedure are to be replaced by new principles of procedure decided by the minister's appointees (the members of the tribunal) and the minister himself. The emphasis in the new rules will be on

brevity and informality, not on whether the evidence presented is properly admissible or has been comprehensively and objectively evaluated. The principle that civil proceedings must be open to the public and the media, which is vital in ensuring a proper level of external scrutiny, will also be undermined by provisions allowing the tribunal member presiding over any matter to decide, at his discretion, whether 'the proper conduct of the hearing' requires that it be closed to the public and the press.[197]

The impartiality of the IP tribunal will also be infringed by provisions stating that part of the money needed to fund it – and to pay the salaries of its members and its staff – is to come from the fines and fees that it imposes through its hearings. This power will be sufficient in itself to undermine the tribunal's independence and objectivity.

In addition, the IP tribunal will have the power to adjudicate on any matter under 'any' legislation already on the Statute Book or still to be enacted in the future. It will also be empowered to make 'any appropriate order' on the matters brought before it. These provisions are unacceptably vague. They are thus also in breach of the rule of law, which requires that all legislation be certain and predictable. Yet the obligation to uphold the 'supremacy' of the rule of law is one of the founding values of the Constitution and cannot simply be ignored.[198]

Moreover, Section 34 of the Constitution gives all South Africans 'the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court, or where appropriate, another independent and impartial tribunal and forum'.[199] The current Patents Court satisfies this requirement, whereas the proposed IP tribunal does not. The DTI's attempt to vest the adjudication of key patent matters in the IP tribunal is thus not only contrary to TRIPS but also in breach of the Constitution's Section 34.

The IP policy will also erode and weaken property rights, even though these are guaranteed by Section 25 of the Constitution and are vital to investment, growth, employment, and prosperity for all South Africans. To take but one example, the granting of a compulsory licence without 'adequate remuneration' to the patent holder will give rise to the indirect or regulatory expropriation of his IP right. Indirect or regulatory expropriation takes place where the state does not acquire ownership, but its regulations deprive the owner of many of the usual powers and benefits of ownership.

As earlier noted, the DTI's 2013 draft policy document claimed that no compensation would be payable in this situation, as the state would not have taken ownership of the patent right. An indirect or regulatory expropriation will nevertheless have occurred, for which compensation should indeed be payable under Section 25 of the Constitution. In addition, many pharmaceutical companies may still have the protection of the 13 bilateral investment treaties (BITs) (with the United Kingdom and other European countries) which the DTI unilaterally terminated in the period from 2012 to 2014. These BITs have 'sunset' clauses under which full compensation for expropriation, whether direct or indirect, remains payable for between ten and 20 years.[200] Moreover, irrespective of how often compensation is in fact

paid, the mere fact that the DTI is contemplating the expropriation of patent rights without compensation will help deter the investment the country so badly needs to increase the growth rate and generate jobs for the more than 6 million South Africans who are currently unemployed.

Still more damaging to property rights is the view, expressed in *Business Day* today, of two of the authors of the 2013 UNDP article. According to Mr Berger and Mr Prabhala, once the Patent Act has been amended, the new legislative framework will make it clear, in relation to patents still to be granted, that 'the right to the intellectual property – a state-sponsored guarantee of market exclusivity – will simply not extend to the circumstances in which compulsory licences may be issued under the amended law'.[201] In other words, the new law will be phrased in a way that prevents patent holders from complaining that their IP rights have been expropriated via compulsory licences. It may indeed be the DTI's intention to change the Patents Act in this way, but whether such amendments would pass muster under Section 25 of the Constitution is doubtful.

Ramifications for innovation

In seeking to limit patent rights, the DTI and health activists have made the plight of AIDS and other patients their key focus. However, this emphasis is misleading when the weakening and/or abrogation of patent rights which they propose cannot lawfully be confined to pharmaceuticals and other health products and will extend to patents in all spheres. The IP policy is also likely to have major ramifications in inhibiting local innovation, undermining South Africa's position in Africa and the world, and eroding the investment climate and the rule of law.

Local innovation

The content of the Patents Act is vital to local inventors. South Africa also has a proud record of domestic innovation in deep-level mining, the development of petrol from coal, and many other spheres. Several important local inventions have also been in the health sector, where the DTI seeks to make patents harder to obtain. Such innovations include:[202]

- the Computed Axial Tomography (CAT) scan, which uses an X-ray source and electronic detectors, as analysed by a computer, to produce a sharp map of the tissues within a cross-section of the body and so helps to detect disease;
- the 'power-free' foetal heart monitor, which uses ultra-sound to monitor a baby's heart rate during labour and relies on solar energy rather than mains electricity;
- the Smartlock safety syringe, which provides improved protection against needle-stick injury and contamination by hepatitis or HIV and has saved countless lives;
- the Lodox scanner, which provides full body X-ray images in just 13 seconds, with a minimal radiation dose and exceptional image quality, and is used in many hospital trauma units as it provides a quick and accurate full-body overview of injuries and foreign bodies;[203] and
- the RoboBEAST, a 3-D printer for ordinary, non-technical people that enables them to print artificial Robohands of any size.

The DTI and other government departments are also trying hard to promote local innovation because (as *Business Day* reported in October 2014) 'both industry and the government are well aware that R&D is an important stimulant to industrial and economic growth'. South Africa's spending on R&D has nevertheless been generally declining, rather than improving, over a significant period. According to Derek Hanekom, who was minister of science and technology until the May 2014 general election, South Africa spent R22.2bn or 0.76% of GDP on R&D in 2011/12 (the same as the ratio reported for 2010/11). But this was a decline from previous years, for the ratio had stood at 0.87% of GDP in 2009/10, at 0.92% in 2008/09, and at 0.93% in 2007/08.[204]

In addition, no real advance is evident in the figures more recently published. In 2013/14, the percentage of GDP spent on R&D was down to 0.73%, though it has since edged up to 0.77%.[205] South Africa is thus still far from achieving the government's current goal of spending 1.5% of GDP on R&D – which would require a doubling of the 2014/15 investment of R29bn to some R60bn a year by 2020. In addition, even if this target is achieved, South Africa will still be spending less than the international average of some 1.77% of GDP.[206]

In Mr Hanekom words, 'the government measures R&D expenditure as a percentage of GDP because it regards [such spending] as a fundamental contributor to innovation-led economic growth and competitiveness'. The government also has three incentive programmes to promote innovation: two of them administered by the DTI and the third (a tax relief initiative) available through the Department of Science and Technology.[207]

The current minister of science and technology, Naledi Pandor, has restructured the National Advisory Council on Innovation (Naci) to give the council easier access to the cabinet on all matters affecting South Africa's National System of Innovation (NSI). Under these revised requirements, the cabinet is obliged to respond to Naci's recommendations and must give reasons if it does not. Perversely, the DTI's IP policy once again seems calculated to stifle the innovation which Ms Pandi and Naci are trying so hard to promote.[208]

The investment climate and the rule of law

One of the most disturbing elements in the IP policy is the implicit proposal (previously made clear in the 2013 draft policy document) to replace the existing patents court with a new patents tribunal. This tribunal, as previously noted, is intended to operate outside South Africa's high court and without being bound by the usual 'legalistic' rules of civil procedure.

The proposed IP tribunal is itself fundamentally at odds with the country's binding obligations under TRIPS, as well as with the constitutional right of access to court. That its administrative decisions will also be subject to judicial review, as health activists have stressed,[209] cannot compensate for these key flaws. At the same time, the importance of effective judicial remedies is difficult to overstate. Writes Judge Harms: '[In the context of intellectual property], there is a significant direct link between judicial system performance and economic development... For intellectual property rights to serve their purpose, effective judicial support is necessary... [A] right without a remedy turns out to be an expensive

fallacy. When judicial support for these specialised rights is feeble, mobilisation of that natural resource [ie, innovation] falters, with considerable losses to the country.'[210]

This warning is a salient one, raising further questions as to why the existing and effective patents court should be replaced by an administrative tribunal. This prospect is disturbing in itself. More worrying still is the possibility that the IP tribunal could serve as a precedent for similar tribunals with decision-making powers over other kinds of property. The patent proposals – which are being communicated to the public as a vital and effective way of saving the lives of millions of AIDS and other patients – could become the thin edge of a much larger wedge, which cumulatively puts the property rights of all South Africans increasingly at risk.

Innovation is also vital to investment, growth, and jobs, as the government is well aware. The known nexus between innovation and prosperity is the key reason the state provides significant incentives for innovation and is trying hard to raise spending on R&D to 1.5% of GDP.

Perversely, the DTI's IP proposals contradict all the state's endeavours to stimulate innovation. They also contradict the key goals of the National Development Plan (NDP): to raise the economic growth rate to 5.4% of GDP a year and reduce the unemployment rate from 25% to 6%. Neither growth nor jobs will increase without much more direct investment – but investors will have little reason to risk their capital, skills, and other resources within South Africa unless they know their property rights, including their intellectual property rights, are secure.

Says the International Chamber of Commerce, the largest business organisation in the world with hundreds of thousands of members in more than 150 countries: 'The protection of intellectual property stimulates international trade, creates a favourable environment for foreign direct investment, and encourages innovation, transfer of technology and the development of local industry, all of which are essential for sustainable economic growth.'[211]

By contrast, the proposed changes in the IP policy will also make it still more difficult to generate growth in the economy, which is expected to stagnate once again this year. By contrast, if South Africa's annual growth rate could be raised to 7% of GDP, the size of its economy would double every ten years. Nothing could do more to build prosperity for all. If South Africa is to reduce unemployment and attendant poverty, foster local innovation, encourage direct investment, and increase its access to sophisticated global technology of every kind, it is vital that the DTI should scrap these damaging proposals.

South African Institute of Race Relations NPC **9th October 2017**

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