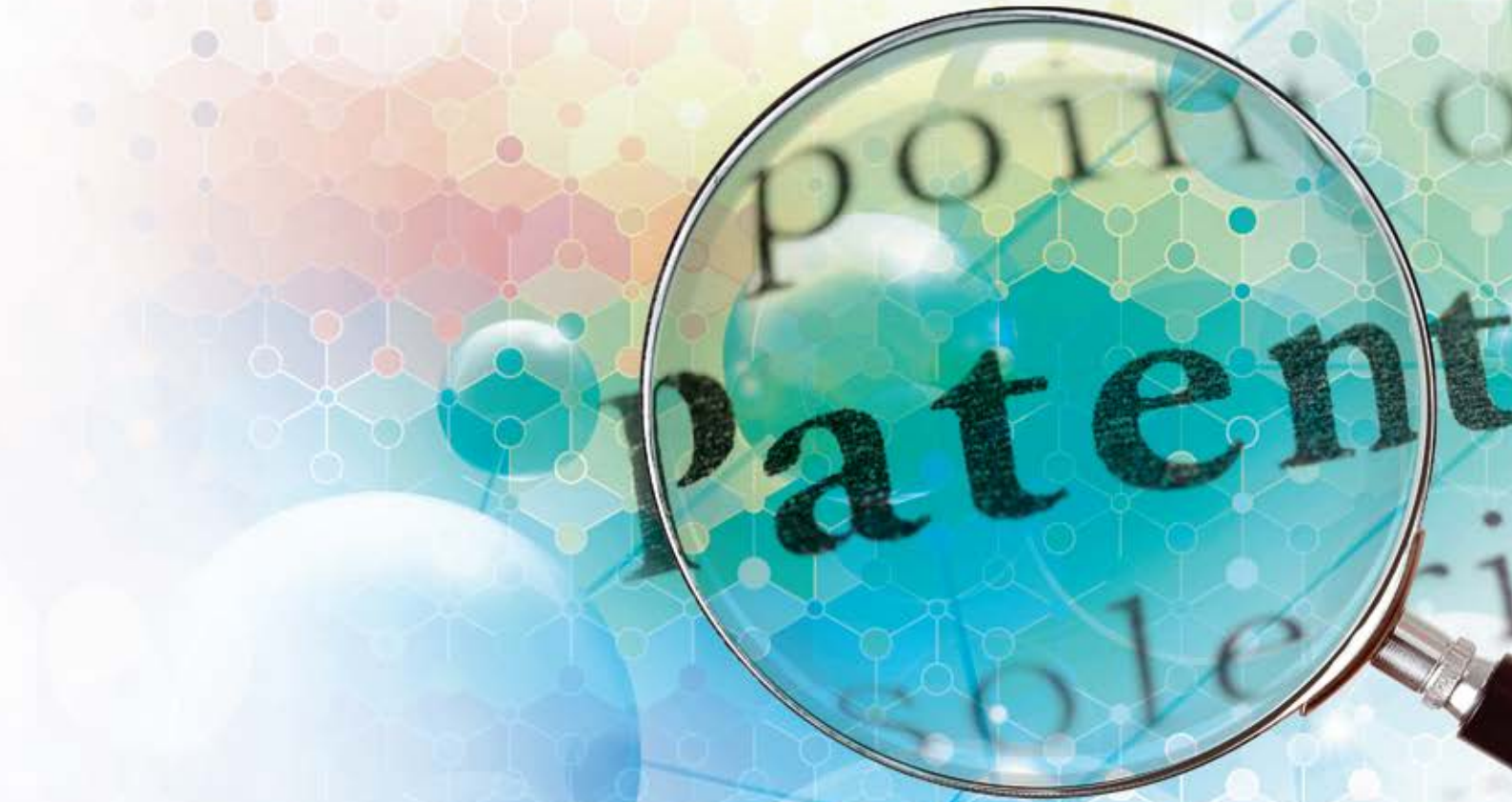
PATENTS AND PROSPERITY

Invention + Investment = Growth + Jobs



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2014

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CHAPTER 1
BACKGROUND AND CONTEXT

Innovation and development

Innovation matters. The 20th century began when aeroplanes, motor cars, and radio were still in their infancy and people were dazzled by their novelty. It ended with spaceships, computers, mobile phones, and the Internet, along with a host of other inventions that have brought enormous benefits to millions of people across the globe.

No list of the inventions made in the 20th century – when innovation progressed at a faster pace than ever before – can begin to be complete. But some of the notable examples include the neon lamp (1910), liquid-fueled rockets (1926), penicillin (1928), the jet engine (1930), radar (1935), the radio telescope (1937), the photocopier (also in 1937), the microwave oven (1943), the kidney dialysis machine (1945), the video tape recorder (1952), the hovercraft (1956), the first personal computer or PC (1957), the audio cassette (1962), electronic fuel injection for motor cars (1966), the first hand-held calculator (1967), the liquid-crystal display or LCD (1971), the laser printer (1976), the first commercial mobile phone (1979), the Apple Macintosh (1983), high-definition television (1990), and the DVD (1995).[1]

The pace of innovation in the 21st century seems likely to accelerate still faster. Already, some of the notable inventions made include the Abiocor artificial heart (2001), Youtube (2005), and the Apple iPhone (2007), which has helped pave the way for other smart phones and given millions of people instant and easy access to the Internet. Other important advances have been made in genetics, cloning, artificial intelligence, robotics, and space exploration, where South African-born Elon Musk has developed a relatively inexpensive re-usable 'Dragon' rocket which has already made a supply trip to the International Space Station. Another extraordinary invention is the world's first 3D printed laptop, which will soon allow people to print out their own laptops in their own living rooms for half the price of conventional machines.

Innovation in the 20th century began with aeroplanes, motor cars, and radio and ended with spaceships, computers, mobile phones and the Internet.

Patents play a vital part in spurring on innovation by giving inventors sole rights to produce and sell their products for 20 years. Patents also protect inventors against people who seek to copy their innovations and thereby reap an unwarranted reward from the creativity, insight, hard work, and costly research of others.

Much of the innovation since 1900 has taken place in the United States, where patent protection has long been strong. The extraordinary number of inventions developed there has played a major part in turning the US into a super-power and the world's biggest economy. Over the past five decades, Japan, South Korea, Singapore, and Hong Kong have also emerged as important innovator countries with high rates of economic growth over many years. China, which introduced limited patent protection in 1985, has used this and other investment incentives to attain rapid rates of economic growth for some 20 years. China now has the second largest economy in the world and receives more patent applications than any other country, including the US (see *Innovation in international overview*, below).

Developing countries which lack the skills for extensive innovation can benefit significantly from inventions made elsewhere by offering them patent protection within their own borders. This is important because patents are territorial in scope, applying only within the countries in which they have been sought and granted. Developing countries that offer reliable protection for patent rights are more likely

to entice innovator companies to start up businesses within their borders, which increases growth and jobs and helps advance the transfer of technology.

Some countries might think they can do better by denying patent rights and simply copying the inventions they desire, but in practice the precise duplication of complex technology is difficult to achieve. It is also likely to hamper trade relations with innovator countries. Hence, states that seek to increase innovation and develop their economies generally benefit more from providing patent protection. China is a good example here. When it first began opening up to the global economy, it thought it might gain more by copying foreign inventions than by protecting them.[3] But by the early 1980s it had recognised the limits of this approach; and in 1985 it brought its first patent law into operation to help boost its attractiveness to foreign direct investment.

Patents give inventors a 20-year 'window of opportunity' for the exclusive exploitation of their innovations.

Patent (and other intellectual property) rights

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 infringements.[4]

As noted, patents are territorial rights, applying only in the country (or region) in which a patent application has been filed and granted. This means that an international pharmaceutical company, for example, must obtain a separate patent in each country in which it seeks an exclusive right to manufacture and/or market a medicine it has developed. However, some basic principles regarding patent rights were laid down as early as 1883 in the Paris Convention for the Protection of Industrial Property. This has since been supplemented by the Patent Cooperation Treaty of 1970, which makes it easier for an inventor to seek simultaneous patent protection in each participating state. In addition, the Patent Law Treaty of 2000 aims to streamline formal procedures for national (and regional) patent applications.[5]

TRIPS and related international agreements

The most important international agreement on patents (and other forms of intellectual property) is currently 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 TRIPS Agreement authorises member states to 'provide limited exceptions to the exclusive rights conferred by a patent'. However, these must not 'unreasonably conflict' with normal patent exploitation or 'unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties'. The nature and extent of these TRIPS 'flexibilities' is further described in due course.[7]

Since the TRIPS Agreement entered into force in 1995, many developing countries have criticised its minimum norms for patent protection, saying these rules bar them from gaining early access to patented medicines at more affordable prices. In the context of the HIV/AIDS pandemic, in particular, international pressure has grown for developing nations to be allowed to depart from these general norms.[8]

On the other hand, the costs of researching and developing safe and effective new drugs are high, especially as failed attempts inevitably far outnumber successes. In addition, writes Jasson Urbach, a director of the Freedom 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'.[9]

The tensions between promoting access to affordable medicines while safeguarding innovation were discussed 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'. This formulation seeks to strike a balance between upholding patent rights over pharmaceuticals and allowing exceptions to them.

The same approach 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', as defined in this way. This document reaffirms their 'ability to use the flexibilities' built into the 1994 document and 'in particular, to promote access to medicines for all'. However, while acknowledging concerns about prices, the declaration also 'recognises that intellectual property protection is important for the development of new medicines'.[10]

The TRIPS Agreement of the World Trade Organisation sets down minimum standards for patent protection in all member countries.

These Doha Declarations were followed in 2003 by the '30 August Decision' of the General Council of the WTO. This Decision waives to a significant extent the usual TRIPS requirement that products made under compulsory licence must be used domestically and not exported. (Under a further agreement reached in 2005, this waiver will be translated into a permanent amendment to the TRIPS Agreement once two-thirds of WTO members have ratified the change.)[11] The content of the Doha Declarations and the 30 August Decision is further outlined in due course.

Patent law in South Africa

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 (CPIC) – 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. [12]

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.[13]

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.

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 urged that the Patents Act be amended to take full advantage of the flexibilities included in the TRIPS Agreement, the Doha Declarations, and the 30 August Decision.

A Draft National Policy on Intellectual Property

The views of health activists are now reflected in the Draft National Policy on Intellectual Property, published by the Department of Trade and Industry (DTI) in September 2013. This document is poorly drafted and often difficult to understand. To grasp its full import, it 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'. This UNDP document was drawn up with significant input from the AIDS Law Project (an activist civil society organisation now known as Section27) and explains more clearly what the Government has in mind. However, though health activists have played a major role in pushing for the changes envisaged, the proposals extend far beyond the health sector and will fundamentally change patent rights over inventions of every kind.

The Department of Trade and Industry (DTI) is pressing ahead with 'an entire change' to South Africa's current Patents Act.

The DTI's policy proposals attracted some 115 comments, almost all of them critical of what the department seeks. The DTI nevertheless remains intent on pressing ahead with the proposals. In late October 2014 it announced its intention to send a bill to Parliament before year-end, saying this would usher in 'an entire change to South Africa's intellectual property laws'. As the *Mail & Guardian* reports, the department is also 'treating the changes as a done deal', even though the bill has yet to be endorsed by the legislature. Hence, the Companies and Intellectual Property Commission, which falls within the DTI, has already begun recruiting some of the staff needed to implement the changes.[14]

Though the content of the bill has yet to be revealed, the DTI and UNDP documents provide important insights into what the ruling African National Congress (ANC) seeks to bring about in what it has repeatedly identified as this 'second' and more 'radical' phase of South Africa's transition.

CHAPTER 2
PROPOSED CHANGES TO PATENT LAW

The DTI/UNDP documents

As the DTI document suggests – and the UNDP article makes clear – the Government's two stated goals are to:

- reduce the prices of medicines by allowing more competition from generics, which are cheaper than patented ARVs and other drugs because (as the DTI's national policy puts it) their manufacturers are 'not involved in research and development';[15] and
- promote local industrialisation by encouraging the growth of a domestic generic manufacturing sector, buttressed by a state pharmaceutical company, which will not only supply the South African market but also export medicines to other countries.

However, these objectives cannot easily be realised so long as South African patents are protected by the current Patents Act. In addition, South Africa's bilateral investment treaties (BITs) with various European countries, including Switzerland and Germany, both home to major pharmaceutical corporations, limit the use of TRIPS flexibilities by prohibiting the direct or indirect expropriation of patent rights. These BITs also entitle the international investors covered by their provisions to 'prompt, adequate, and effective compensation' in the event of any expropriation of their intellectual (or other) property. This helps explain why South Africa is intent on terminating many of these agreements and replacing them with the misleadingly named Promotion and Protection of Investment Bill of 2013 (the Investment Bill), under which the State's acquisition or limitation of patent rights may not qualify as an 'act of expropriation' or warrant the payment of any compensation at all.

The DTI wants to make patents harder to obtain, easier to bypass, more difficult to enforce, and cheaper for the State to take.

In order to achieve its stated goals, the DTI, as further explained in the UNDP article, seeks to change the relevant rules in seven key spheres. In a nutshell, it wants to:

- make new patents harder to obtain;
- expand 'compulsory licensing' to bypass patent protections;
- allow the exporting of products made under compulsory licence;
- limit the remedies available to patent holders;
- replace the present patents court with a new patents tribunal;
- empower the State to acquire or restrict patents without having to pay compensation; and
- put an end to BITs that give foreign investors a 'TRIPS-plus' level of protection.

These proposals – and the extent to which they comply with the TRIPS Agreement, the Doha Declarations, or other relevant laws – are further described below.

Making new patents harder to obtain

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'.[16]

South Africa is a 'depository' or 'non-examining country', in which all patent applications made to the Patent Office – now, as noted, the CIPC – are granted, provided a detailed patent 'specification' (or description of the invention) is provided and the necessary fees are paid.[17] 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 suggest 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. The UNDP document adds that it is 'expensive and time-consuming' to contest the validity of a patent after it has been granted. It thus seeks the introduction of an examination system which would prevent new patents from being granted until objections from civil society organisations have been heard and adjudicated upon. [18]

South Africa used to have an examination system, but had to abandon it in 1978 because it 'never had the people' with the specialist skills required.

However, as a patent lawyer points out, 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.[19] Moreover, the depository system has safeguards too, 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.[20]

Also relevant is the fact that South Africa used to have an examination system, but had to abandon it in 1978 because it lacked the necessary skills. Notes 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.' [21]

The DTI and UNDP documents nevertheless seek to end South Africa's depository system and replace it with an examination one, saying this is necessary to stop the common practice by pharmaceutical companies of 'evergreening' their patent rights. According to the UNDP article, 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) should 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 document, pharmaceutical companies nevertheless often obtain new patents on the basis of such inconsequential improvements to their existing medicines.[22]

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 'evergreen' their patents by 'developing new formulations...and new forms of existing medicines', which in fact offer 'nothing new' and 'have no therapeutic benefits'.[23]

Pharmaceutical companies, the TAC adds, 'extend their monopolies through the use of secondary patents. Companies will...make obvious minor improvements or modifications to a known drug in

order to gain a secondary patent on the existing compound... A Yale University study demonstrated that secondary formulation patents added an average of 6.5 years of patent life...and patents on new forms...add 6.3 years'.[24]

However, even if this assertion is true in the United States or other countries, the TAC's criticism 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' the original invention. However, it also states that a patent of addition expires at the same time as the original patent.[25] Hence, the original patent term cannot be 'extended' in South Africa through minor improvements in the way the TAC suggests.

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. However, health activists seem to disregard this option.[26] In addition, the validity of a second patent granted in these circumstances can always be challenged in the patents court.

The UNDP article overlooks these factors. Instead, it urges South Africa to build on experience in India, where (it says) the introduction of an examination and objection system, coupled with restrictions on 'evergreening', has resulted in the rejection of many patent applications. It cites a recent study showing that some 77 (70%) of the 110 patents granted by the Food and Drug Administration (FDA) in the United States would have been barred in India under the stricter patent system introduced there in 2005. If the same approach were to be followed in South Africa, this would 'result in fewer and better quality patents'. Fewer patents, in turn, would 'result in greater generic competition, which in turn would lower drug prices and ensure a sustainable supply of drugs from multiple manufacturers'.[27]

The UNDP document effectively suggests that allowing objections before, rather than after, the granting of patents would be a 'silver bullet' that would not only exclude unwarranted patent rights but also solve a host of other obstacles to the manufacturing of pharmaceuticals in South Africa. These barriers range from rigid price controls on medicines to electricity shortages, high labour costs, inadequate transport logistics, and poor skills and productivity compared to countries such as India and China (see *Ramifications for industrialisation*, below).

Despite the weaknesses in the UNDP article, the DTI's draft policy is clearly in line with it. The policy document repeatedly urges the adoption of 'strict rules' on patentability, which would prevent the granting of patents over inventions not sufficiently new. Like the UNDP article, it also recommends shifting to an examination system which would make the granting of patents more difficult to secure. To obtain the necessary skills, the Companies and Intellectual Property Commission within the DTI is already looking for 20 university graduates to appoint as patent examiners in April 2015. It says it will then train them in the complexities of patent review,[28] but this will hardly suffice.

If there are not enough patent examiners, there will be long delays before patents are granted and the whole patent system could fall apart.

A recent article in the *Mail & Guardian* cautions: 'Twenty patent examiners will find it difficult to make a dent in the about 7 000 patents granted by the Companies and Intellectual Property Commission each year.' Given the number of patent applications received, 110 examiners would be a more realistic number. David Cochrane, a patent attorney at Spoor & Fisher, adds that any benefits 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.'[29]

In practice, even if the patent system avoids such a collapse, the mooted change will add significantly to the costs and complexities in obtaining patents. Ironically, the burden will fall most heavily on local inventors lacking the experience to navigate the new requirements. By contrast, multinational corporations seeking to supplement patents obtained elsewhere with a South African one too will find it easier to cope because they are already well versed in the procedures and are likely to have more resources to draw on.[30]

The time needed for examination will inevitably also 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 an application) 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.

Expanding the scope for compulsory licences

According to the UNDP document, though stricter patentability criteria and the introduction of an examination system would dramatically reduce the number of patents granted on medicines, there would still be many instances in which 'patents would remain a barrier to access'. This would be the case with all 'the truly innovative medicines' still to be developed in the future. It would also apply to the 'many... drugs of public health importance [that] are already under patent' and so cannot be copied.[31] The UNDP document thus also seeks new rules making it easier to bypass existing patents by greatly extending the scope for 'compulsory licensing'.

Voluntary versus compulsory licences

Where patent holders see commercial advantage in such agreements, they 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.

Compulsory licences are different 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.

The TRIPS Agreement allows 'limited exceptions' to patent rights, provided these do not 'unreasonably prejudice' the patent owner.

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. In addition, such licences may be granted only by the patents commissioner, and then only after a comprehensive hearing in the patents court. Moreover, in deciding what royalties should be paid, the patents commissioner is expressly enjoined to consider 'the research and development' (R&D) undertaken by the patent holder. He must also take into account the terms and conditions 'usually stipulated' in voluntary licence agreements.

The UNDP article criticises these requirements, saying they are likely to 'produce excessively high royalty rights' and make for 'lengthy litigation during which the issuance of a compulsory licence will be delayed'.[32] It thus seeks various changes to the Patents Act, which it says are in line with TRIPS flexibilities and will make compulsory licences both easier and cheaper to obtain.

Article 30 of the TRIPS Agreement does indeed allow 'limited exceptions' to the exclusive rights conferred by a patent. However, as earlier noted, 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'.[33] According to the UNDP article, this wording authorises the granting of compulsory licences in wide-ranging circumstances. However, the amendments it recommends go significantly beyond the scope of the TRIPS exceptions, as further described below.

A regulatory straitjacket

Both the UNDP document and the draft national policy recognise the benefits in voluntary licences but warn that these agreements may not be easy to secure unless the regulatory framework puts pressure on patent holders to enter into them.[34] Towards this end, the UNDP article urges 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). Moreover, any failure to meet these conditions should be seen as prima facie evidence of 'unreasonable conduct' on the part of a patent holder, which in itself would attract further negative consequences (see *Anti-competitive conduct*, below).

Compulsory licences would have to be granted after, say, 60 days of negotiation and at royalties of, say, 3% of the price of the copied products.

The UNDP document claims that such rules would be in keeping with TRIPS, which says that a compulsory licence is permitted if the would-be licensee has first 'made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions', and 'such efforts have not been successful within a reasonable period of time'. Moreover, TRIPS seeks only 'adequate remuneration' for the patent holder, which this new regulatory framework would allegedly provide.[35]

What Article 31(h) of the TRIPS Agreement actually says is that the patent holder is entitled to 'adequate remuneration in the circumstances of each case, taking into account the value of the authorisation' to use the patented product without the patent holder's consent. [36] Moreover, when TRIPS says that 'adequate remuneration' should reflect the value of the compulsory licence, this does not necessarily mean that royalties may be based on the price of the copied products. It could equally mean that royalties must take into account the full market value of the patent the compulsory licensee is being permitted to use.

According to the UNDP article, Canadian legislation provides a suitable model of what TRIPS envisages, for it allows compulsory licences on medicines intended for export, 'caps the royalty rate at 4% of the price of the generic products, and adjusts the royalty rate downwards according to the importing country's rank on the UNDP Human Development Index'. (This index, developed by the United Nations Development Programme, measures nations according to three basic criteria: average years of schooling, gross national income per capita, and life expectancy at birth.) The UNDP article suggests that South Africa adopt a similar approach, in which a 'reasonable royalty' would be laid down by regulation. The stipulated royalty rate should also be adjustable downwards so that it could be reduced for patent holders that have engaged in anti-competitive conduct.[37]

However, the Canadian legislation cited in the UNDP article has a narrow ambit. It was adopted in 2004 under the 30 August Decision of the WTO (see *Rights to export*, below); and its purpose is to help developing countries which lack manufacturing capacity to import generic ARVs, provided that a number of stipulated conditions are met.[38] Hence, this statute hardly provides a model for what royalty payments should be for copied products that are intended for use within Canada itself, or which fall outside the health sector. The UNDP document omits to mention these factors.

National emergency or 'extreme urgency'

Though prior negotiation is generally needed before a compulsory licence can be issued, the TRIPS Agreement says that that this requirement 'may be waived by a member state in the case of a national emergency or other circumstances of extreme urgency'. The Doha Declaration on TRIPS and public health adds that 'each member state has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency'.[39]

However, South Africa's Patents Act makes no mention of national emergencies or situations of extreme urgency, and has no 'expedited procedure' for the issuing of compulsory licences in these circumstances. This omission needs to be corrected, the UNDP article urges. In addition, given the magnitude of the HIV/AIDS pandemic in South Africa, the new rules should allow the minister (or the director general) of health simply to publish a notice in the *Government Gazette* stating that a national emergency exists or that a 'situation of extreme urgency' pertains. Once such a notice has been gazetted, the patent authorities should be obliged to grant relevant compulsory licences, for the new rules (as in India) should exclude any discretion in this regard. These compulsory licences should be issued on 'the standard terms' regarding royalty payments, as laid down in the new regulatory framework. Moreover, though a patent holder would be able to seek judicial review of a decision to grant a compulsory licence (as the Bill of Rights requires), the new rules should stipulate that such proceedings would not 'ordinarily be permitted to prevent the compulsory licence from being used' pending the finalisation of this review.[40]

The State could use any patented invention after brief negotiations and against limited royalties, without having to pay compensation for expropriation.

These proposals assume that the proclamation of an AIDS emergency would suffice to compel the granting of compulsory licences over any number of ARVs – and that this would be in keeping with the TRIPS Agreement and the two Doha Declarations. But TRIPS authorises only 'limited exceptions' to patent rights, while the Doha Declarations emphasise the need for 'research and development into new medicines'[41] and 'the importance...of intellectual property protection' in promoting this. The UNDP document thus overlooks the careful balance that both TRIPS and Doha seek to maintain.

Government use

Section 4 of the Patents Act says 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'.[42]

Under these provisions, as the UNDP article stresses, a patent holder cannot be compelled to allow the Government to use a patented invention without either his agreement or a prior ruling by the commissioner to that effect. In addition, such a ruling can be issued only after 'potentially lengthy and expensive court proceedings'. According to the article, this overlooks a TRIPS flexibility which allows the issuing of compulsory licences without prior negotiation 'in cases of public non-commercial use'.[43]

The UNDP article urges that the Patents Act be amended to reflect this flexibility. This, it says, would 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 national policy adds that no compensation for expropriation would be payable to the patent holder in these circumstances, as the patent holder would still retain its patent. Says the DTI 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.'[44]

The Investment Bill adds that there is no 'act of expropriation' in 'the issuance of compulsory licences granted in relation to intellectual property rights,...to the extent that such issuance is consistent with applicable international agreements on intellectual property'.[45] This provision assumes that the TRIPS Agreement endorses extensive governmental use of patents in the health sector and beyond.

The TRIPS Agreement does not attempt to define 'public non-commercial use',[46] perhaps because it sees the clause as self-explanatory. The activist view is that any governmental use will fit within it, but this is by no means clear. Moreover, if the aim 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 (see *Rights to export*, below), it is doubtful whether this would count as 'non-commercial' use. For inventions outside the health sector, any similar claim would be even more difficult to sustain.

Public health grounds

According to the UNDP document, the Patents Act should also include a 'catch-all' provision allowing the issuing of compulsory licences 'on public health grounds'. This would allow either a generics manufacturer or a civil society organisation, such as Section27, to seek a compulsory licence on this basis and 'in the public interest'. Says the document: 'Such a ground would effectively serve as a "catch-all" to allow compulsory licences to be granted in situations that may not necessarily fit neatly' into any of the other grounds. The necessary amendments should also allow 'an expedited administrative procedure', with a fixed timetable for prior negotiations (where these are necessary), clear rules on the maximum royalties payable, and 'no possibility of obtaining a stay on the operation of the licence pending any review or appeal'.[47]

Allowing the issuing of compulsory licences on general public health grounds would fit within the Doha Declaration on TRIPS and public health, which gives each member state 'the freedom to determine the grounds' on which compulsory licences are to be granted.[48] However, TRIPS requirements regarding adequate remuneration and effective enforcement of patent rights would still apply – and would not easily be satisfied by these proposals.

'Abuses' of patent rights

As earlier noted, Section 56 of the Patents Act already empowers the patents commissioner to grant compulsory licences. However, it also makes it clear that this may be done solely to counter four types of 'abuse' by patent holders, these being:[49]

- 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 '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 UNDP document criticises the Act for failing to identify these abuses as amounting to 'anti-competitive' practices. It wants the statute amended to rectify this omission. In addition, it wants the new rules to state that any proven anti-competitive practice is sufficient in itself to warrant the granting of a compulsory licence (see *Anti-competitive conduct*, below).

Compulsory licences would also be available on public health grounds and for any 'abuse' of patent rights, as broadly defined.

The UNDP document also wants the existing provisions in the Patents Act expanded to include various definitions of conduct that would be 'deemed' to be anti-competitive. For example, the clause dealing with 'excessive pricing' should also state that 'a price charged by a patent holder that bears no reasonable relation to the marginal or average variable cost of manufacturing the item shall be deemed to be unreasonable'. In addition, the new wording should state that a patent holder will 'be deemed to have refused to grant a licence on reasonable terms' if he fails to grant a licence 'in accordance with stipulated royalty guidelines and within a specified time period'.[50]

The UNDP article assumes that these provisions would be in keeping with the TRIPS Agreement. However, there is little in TRIPS to support so wide an interpretation of the 'abuse' of patent rights. In addition, the proposed 'deeming' clauses overlook the emphasis in TRIPS on the abuse of IP rights having to be 'determined' through judicial or administrative processes, rather than presumed.[51]

Anti-competitive conduct

The TRIPS Agreement recognises (in Article 8) that 'appropriate measures...may be needed to prevent the abuse of intellectual property rights,...*provided they are consistent*' (my emphasis) with other TRIPS provisions. Article 31 of TRIPS adds that 'members are not obliged' to engage in prior negotiation or apply the usual export constraints where the 'unauthorised' use is 'permitted to remedy a practice determined after judicial or administrative process to be anti-competitive'. In this instance, the remuneration payable to the patent holder may also be reduced.[52] These provisions make compulsory licences against anti-competitive conduct particularly valuable, as the UNDP document points out.

The TRIPS Agreement gives various examples of 'anti-competitive practices in contractual licences', saying that 'some licensing…conditions…which restrain competition might have adverse effects on trade…and the transfer…of technology'. These practices, it says, may include conditions that prevent licensees from challenging the validity of patents, for instance. These are arguably the only anti-competitive practices that the Agreement recognises, but the UNDP article nevertheless suggests that TRIPS leaves it open to member states to adopt their own definitions of anti-competitive conduct.[53]

In South Africa, relevant definitions are laid down in the Competition Act of 1998, which 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 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, facilities deemed essential include infrastructure such as railway bridges, local electricity transmission networks, and sports stadiums. However, the South African definition is wider than the US one, allowing a broader interpretation of its meaning.[54]

Prior negotiations are not needed where compulsory licences are granted against anti-competitive conduct. Constraints on exporting copied products fall away.

According to the UNDP article, South Africa's Competition Act is still 'largely untested in the realm of intellectual property'.[55] However, two recent examples point to the wide-ranging circumstances in which patent holders could be compelled to grant compulsory licences to counter anti-competitive practices.

The first case began in 2002, when the TAC and other various others 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.[56]

In 2003 the commission ruled against the companies, saying both 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 the competition commissioner, Menzi Simelane, this 'essential facility' was the patented formula for their AIDS drugs. An editorial in *Business Day* warned that this was a 'novel interpretation of competition law', which would undermine patent protection in South Africa, not only in the health sector but also in all other spheres.[57]

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 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.[58]

As the UNDP article records, the second case began in 2007, when the AIDS Law Project, acting on behalf of the TAC, filed a complaint with the Competition Commission against Merck Sharp & Dohme (MSD), the South African subsidiary of the US multinational corporation Merck & Co Inc. The complainants alleged that MSD was 'refusing to license other firms to import and/or manufacture generic versions of EFV [efavirenz] on reasonable and non-discriminatory terms'. They said 'this threatened access to comprehensive treatment for HIV/AIDS', negatively affected 'consumer welfare', and amounted to an 'exclusionary act' with significant 'anti-competitive effects'. They also argued that MSD was 'in any event selling its ARV medicines at cost' and so was 'unlikely to suffer any real harm' if they were compelled to license'.[59]

An overly broad interpretation of competition law can make patent rights 'illusory' and undermine innovation, to the detriment of consumers.

Again, a settlement was reached. Here, MSD agreed to license four generic drug companies (two local producers and two local importers) to bring EFV products to market. The company also waived any right to a royalty, and agreed that all licensed products could be sold not only in South Africa but also in ten other Southern African countries. The TAC responded by withdrawing its complaint, saying there were now 'a sufficient number of competitors to ensure that EFV prices were kept as low as was reasonably possible'.[60] However, since MSD was already selling EFV at cost before the case began, it is questionable whether any significant reduction in prices could thus be achieved.

Both these cases have disturbing connotations. Was the MSD guilty of anti-competitive conduct when it was already selling EFV at cost? Was Mr Simelane correct in his 2003 ruling that GlaxoSmithKline and Boehringer Ingelheim were engaged in 'excessive pricing' when their ARV prices were reportedly already among the lowest in the country? In addition, was the commissioner's 'novel' interpretation of an 'essential facility' 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:[61]

> 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 questionable 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'.[62]

It is also doubtful if the outcomes of the 2003 and 2007 cases 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, in both these cases, the patent holders 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 and 'unreasonably prejudiced' their legitimate concerns.

Despite the weaknesses in its perspective, the UNDP article urges that the Patents Act be amended to state that any proven anti-competitive conduct will justify the issuing of a compulsory licence. The new rules, it says, should also expressly provide that 'limitations on exports and the need for prior negotiations will not apply' in these circumstances.[63] Once again, it also wants royalties to patent holders to be limited to, say, 3% of the price of the copied products.

The aim is to circumvent the usual TRIPS rule that products made under compulsory licence must be used 'predominantly' in domestic markets.

If these changes are introduced, it will become much easier for generics manufactures to obtain compulsory licences and then use these to produce and sell copies of patented medicines both locally and abroad. The absence of export restrictions in these licences could allow these manufacturers to sell their copies in a host of countries, including many nations where the patented originals are on sale at higher prices. This consequence would not be confined to the health sector, of course, but could also apply to any patented invention that competitors might want to exploit on exceptionally favourable terms for themselves.

The DTI's draft national policy is not as overt as the UNDP article in spelling out the changes it seeks. However, it repeatedly stresses the need for South Africa to 'change the Patents Act to incorporate patent flexibilities, as contained in the TRIPS Agreement and the Doha Decisions'. It adds that these agreements allow 'resort to compulsory/voluntary licensing...and the application of competition laws to cater for public health access'. It also stresses that TRIPS 'empowers member states to curtail intellectual property rights through competition laws if there are abuses'.[64] These clauses indicate that the DTI does indeed seek the same changes as the UNDP document recommends.

Rights to export

The normal rule under the TRIPS Agreement is that products made under compulsory licence must be used 'predominantly for the supply of the domestic market'.[65] However, as the UNDP document points 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 document 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.' [66]

As earlier noted, this TRIPS constraint on exports is indeed excluded where the patent holder has been found guilty of anti-competitive practices. Assuming such practices can indeed be broadly defined, this makes compulsory licences against anti-competitive conduct particularly useful. In addition, so the UNDP article argues, the usual constraint on exports can be circumvented to a significant extent under the 30 August Decision of the General Council of the WTO.

This decision, adopted in 2003, seeks to make it easier for countries which lack manufacturing capacity to import generic medicines being made under compulsory licence elsewhere. However, various conditions must be met if this waiver is to apply. 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'.[67]

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 their exports 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.[68]

Such limitations are clearly intended to prevent the waiver from being abused. Developing countries have complained about the practical difficulty of meeting them, prompting further discussions on the issue by the TRIPS Council in 2010. As yet, however, the 2003 conditions remain in place.

The 30 August Decision does provide 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.[69]

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.[70] This argument is legally sound, but the SADC market is a small one and would probably not be capable in itself of helping to sustain the expanded pharmaceutical industry the DTI seeks.

To circumvent this problem, the UNDP article argues that South Africa does not need to comply with the 30 August Decision – and is thus entitled to export generics beyond the limits of the SADC region. The article 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 advises that the export 'procedure should not be made more cumbersome than necessary', adding: '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'. [71] 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 patent in issue.

However, if South Africa were to follow these recommendations, it would clearly be in breach of the TRIPS Agreement and the 30 August Decision. These agreements simply do not allow the untrammelled exporting of generic medicines – let alone of other goods – produced under compulsory licence.

Health activists want to protect generics manufacturers, but not innovator companies, against investment losses.

Limiting the remedies available to patent holders

At present, the Patents Act allows a patent holder to enforce its intellectual property right by applying to the patents commissioner for an interdict, the delivery up to it of all infringing products, and damages. However, the UNDP document warns against such remedies, saying: 'The risk of incurring harsh penalties in infringement proceedings...could pose a significant disincentive for domestic companies to enter the market with affordably priced generics. The mere threat of being enjoined from selling its product, after investing considerably in bringing a product to market, could deter a generic company from making such investments at all.'[72]

As this passage shows, health activists understand the importance of protecting the investments of generics manufacturers – which, by definition, spend little on R&D – but see little reason to protect the much larger investments of the pharmaceutical companies engaged in original research.

According to the UNDP document, it is legitimate to 'impose reasonable limits on the remedies available to patent holders' in the health sector, where most patents are 'likely to be owned by foreign entities' and their South African subsidiaries.[73] However, this overlooks the fact that roughly 10% of patent applications are lodged by South Africans – who also need to be able to enforce their patent rights, and whose inventions commonly lie outside the health sphere.

Remedies against infringement are to be limited, which will affect all patent holders – not only multinational corporations.

Interim interdicts

At present, a patent holder can apply for an interim interdict ordering a firm which is allegedly infringing its patent to stop making or selling the product in issue pending the final determination of the case. Since no appeal can ordinarily be brought against such a preliminary order, an interim interdict (in the words of the UNDP document) is 'one of the most powerful tools' by which patent holders can prevent the sale of unauthorised copies of their patented products.[74]

Though the Patents Act provides for the granting of interdicts, it does not expressly refer to interim as opposed to final ones. However, interim orders are generally available under the common law – though only if a number of requirements are fulfilled. In essence, the patent holder must be able to show that 'he has no other satisfactory remedy' and is likely to suffer 'irreparable harm if the interim relief is not granted'.[75]

The UNDP document notes that the granting of interim interdicts cannot be barred altogether, because Article 50 of TRIPS uses peremptory (rather than permissive) wording in stating that 'the judicial authorities [in a member state] *shall* have the authority to order prompt and effective provisional measures' (my emphasis). The Article also says that states must be able 'to prevent the entry' of infringing products 'into the channels of commerce' within their borders.[76]

The granting of interim interdicts can nevertheless be constrained, the UNDP article goes on. This can be done by amending the Patents Act to provide that, 'in any application for an interim interdict in infringement proceedings, the payment of royalties shall be deemed to be a satisfactory remedy unless the plaintiff can prove the existence of exceptional circumstances in which such royalties would not suffice'.[77]

However, this proposal ignores peremptory TRIPS wording requiring 'prompt and effective provisional measures'. It also disregards Article 41 of TRIPS, which says that member states must ensure 'effective action against any act of infringement,...including expeditious remedies to prevent infringements, and remedies which constitute a deterrent to further infringements'.[78] Limited royalties in the place of an interim interdict will hardly satisfy this obligation.

Final interdicts

Under the Patents Act, final interdicts may be granted once an infringement of a patent has been proved. In addition, Article 44 of the TRIPS Agreement says that 'the judicial authorities of a member state *shall* have the authority [my emphasis] to order a party to desist from an infringement, inter alia, to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right'.[79]

The UNDP article sidesteps this mandatory wording, saying that the Article allows member states to 'limit the remedies available' to the payment of adequate remuneration, in certain circumstances. However, these circumstances arise only where the TRIPS requirements regarding 'government' use not only apply but have also been fulfilled[80] – a limitation the UNDP document fails to acknowledge.

Judge Louis Harms, a retired vice president of the Supreme Court of Appeal, has pointed out that 'final interdicts are granted as a matter of course in South Africa', as a failure to do so would 'amount to granting the infringer a compulsory licence'. Judge Harms also recognises that this approach might perhaps need to be changed where public health interests are in issue. However, the UNDP article goes

much further than this, urging that the Patents Act be amended to provide that a final interdict 'shall not be granted' if it is 'in the public interest' to deny it, or if the payment of damages is 'sufficiently adequate to compensate the patent holder'.[81]

This wording would be wide enough to apply both within and outside the health sector and could bar the granting of final interdicts in many instances. However, this overlooks the importance of effective remedies against patent infringement. Writes Judge Harms: 'Without effective legal remedies, a court cannot enforce IP rights effectively.... [Yet] the fact that the South African judiciary has been able and willing to give effect to IP rights and the country's international obligations...has given an added impetus to investment, both local and foreign.'[82]

The UNDP article also recommends a further amendment to the Patents Act that would allow the defendant in any infringement proceedings to counter-claim for a compulsory licence on any of the grounds earlier outlined, including the catch-all 'public interest' one. Patent holders would then know that any attempt to enforce their intellectual property rights could invite applications for compulsory licences which would be difficult for them to resist. But this contradicts the emphasis in TRIPS on the need for effective remedies in the event of infringement. It also overlooks a TRIPS provision stating that 'procedures' for the enforcement of intellectual property rights must be 'fair and equitable'.[83] Penalising patent holders for trying to enforce their rights would hardly satisfy this requirement.

Replacing the patents court with a patents tribunal

The UNDP document criticises the fact that patent matters are currently heard in the patents court, where the relevant rules of civil procedure make for complexities, costs, and delays. It recommends that these court proceedings 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 would be limited by another new rule, under which the use of a compulsory licence granted by such a tribunal could not be stayed (placed on hold) pending the finalisation of the review.[84]

The DTI's draft national policy adds that the 'enforcement of intellectual property is expensive and that judicial systems are under severe strain'. It thus proposes 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 says, should not be 'dominated by lawyers' or subject to high court rules, as these make for 'highly technical and legalistic procedures'.[85]

In urging this change, the UNDP article argues that the TRIPS Agreement does not require judicial, rather than administrative, proceedings. But this overlooks 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.' Moreover, says Article 49, 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. [86]

The patents court would be replaced by a patents tribunal, which would be freed from the need to follow 'technical and legalistic' high court rules.

Termination and acquisition of patent rights

According to the UNDP document, the Patents Act should acknowledge that compulsory licences may not always suffice to end anti-competitive practices or other abuses. In addition, it says, 'there may be extreme situations' in which it would be in the public interest for the State to revoke or acquire a patent, rather than seek a compulsory licence.[87]

Revocation after compulsory licensing

Revocation of patent rights is dealt with under Article 5 of the Paris Convention, which the TRIPS Agreement requires all member states to uphold. According to the Paris agreement, revocation may be appropriate where compulsory licences have not succeeded in 'preventing the abuses which might result from...the exclusive rights conferred by the patent, for example failure to work' (or exploit) the invention.[88]

The State would have wider powers to revoke patents, and also to acquire them for 'just' compensation without the patent holder's consent.

Where a patent holder fails to exploit his invention, neither he nor anybody else is able to benefit from the innovation, which is contrary to public policy. However, such a failure to work is the only example of 'abuse' included in the Convention. The Paris agreement adds that no compulsory licence may be sought on this basis for three years after the granting of the patent, and that the licence must be refused if the patent holder 'justifies his inaction by legitimate reasons'. Moreover, once a compulsory licence has been issued, 'no proceedings for the forfeiture or revocation of the patent' may be brought for two years thereafter.[89]

The UNDP article criticises Section 61 of South Africa's Patents Act for omitting to recognise a failure to work as a ground for revoking a patent. (The 1978 statute does, however, allow revocation where a patent is invalid – for example, because the invention is not in fact patentable, or its granting has been tainted by fraud.) The UNDP document thus wants the statute amended to allow a patent to be revoked after two years from the granting of the first compulsory licence, provided this licence has not been enough to prevent 'abuse'.[90]

The UNDP article fails to acknowledge that three years must elapse from the granting of a patent before the first compulsory licence may be sought. More seriously, the UNDP document seeks to extend the meaning of 'abuse' to include anti-competitive practices, which the Paris Convention does not in fact identify as a valid reason for patent revocation (see *Anti-competitive conduct*, above).

State acquisition

The Patents Act allows the relevant minister (currently the minister of trade and industry, it would seem) to acquire 'any invention or patent' on behalf of the State, 'on such terms and conditions as may be agreed upon'. This restricts state acquisition to instances where agreement with the patent holder can be reached and may not be enough (the UNDP document says) to satisfy the public interest. The statute should thus be changed to allow the State to acquire a patent in exchange for 'just' compensation, even where the patent holder does not agree.[91] However, there is nothing in the TRIPS Agreement or the Doha Declarations to sanction state takings on these terms.

Neither TRIPS nor Doha supports the UNDP article's further recommendation – that the Government should also be able to expropriate patents 'in those rare and extreme cases in which outright expropriation would be appropriate'. Such acquisition, the UNDP document goes on, would be 'subject to compliance with Section 25, *insofar as it deals with expropriation*' (my emphasis).[92] Section 25 is the property clause in the Bill of Rights and it requires the payment of 'just and equitable compensation' for any property expropriated by the Government. However, Section 25 also draws a distinction between expropriation and other 'deprivations' of property at the hands of the State. The Investment Bill goes further, expressly providing that various actions by the State do not qualify as 'acts of expropriation' and thus need not be accompanied by any compensation at all.

Promotion and Protection of Investment Bill of 2013

The Investment Bill was tabled for comment by the DTI in November 2013, the month after the UNDP document was published. The current status of the Bill remains uncertain, but in May 2014 the minister of trade and industry, Rob Davies, said it would be submitted to the Cabinet for approval in the near

future. More recently, another DTI spokesman has confirmed that the measure is soon to be put before Parliament.[93]

What changes have been made to the Investment Bill in the interim remain unknown. In its initial formulation (the only version currently available), the Investment Bill applies to virtually all property, including intellectual property, which is used 'for commercial purposes'. Some of the Bill's provisions echo the Constitution in entitling the owner of such property to 'just and equitable compensation' in the event of expropriation. However, other provisions in the Bill seek to narrow the meaning of expropriation by stating that various actions by the Government 'do not amount to acts of expropriation' at all.[94]

Among the governmental actions listed in the Investment Bill are:

- 'measures which result in the deprivation of property but where the State does not acquire ownership of such property', provided that 'there is no permanent destruction of the economic value of the investment'; and
- the 'revocation or limitation…of intellectual property rights' to the extent that this is 'consistent with applicable international agreements'.

The first of these provisions is based on a majority decision by the Constitutional Court in the *Agri SA* case. This ruling, handed down in April 2013, found that no expropriation had taken place when the State acquired an unused mining right as 'custodian' for the people of South Africa, rather than as owner. This suggests that, if the State were to take a patent to a new ARV, not as owner but rather as custodian for the disadvantaged, the first part of the test in the Investment Bill would be satisfied. Moreover, if the State were then to allow various generics manufacturers to apply to it for licences to exploit the patent, there would be no 'permanent destruction of the economic value' of the patent, which would continue to be used by others. This would satisfy the second part of the test.

In these circumstances, there would seemingly be no expropriation – and no compensation to be paid – under the principles laid down in the Investment Bill. The validity of the Bill might also be difficult to contest when the Constitutional Court, in the *Agri SA* case, has already endorsed a similar approach. However, there is also a fundamental difference between an unused mining right – often an unexpected windfall – and a patent granted after onerous and often very costly R&D. This suggests that the *Agri SA* judgment may not provide sufficient judicial authority for the uncompensated taking of patents by the State.[95]

The second relevant provision in the Investment Bill says there is 'no act of expropriation' if the State revokes or limits a patent, provided its conduct is 'consistent with applicable international agreements'. Such agreements would, of course, include the Paris Convention, the TRIPS Agreement, the Doha Declaration, and the 30 August Decision. This clause in the Investment Bill implies that these four agreements would sanction state action of this kind. However, there is little in the wording of these international instruments to support this view. All four allow exceptions to patent rights, but only in limited circumstances, for limited periods, and subject to strict safeguards. None allows for either the direct or indirect expropriation of patents, and all of them call for patent rights to be upheld except in the limited instances in which some derogation is permitted. This provision in the Investment Bill is thus more likely to be in breach of relevant international agreements than in conformity with them.

No compensation may be payable where the State takes a patent as custodian for the disadvantaged and then licenses others to copy and sell the invention.

Bilateral investment treaties and their 'TRIPS-plus' requirements

The UNDP document makes no mention of bilateral investment treaties (BITs), but the DTI's draft national policy document warns that bilateral trade agreements can 'undermine' general agreements, such as TRIPS. 'A good example is where certain developing countries are forced to...renounce the

patent flexibilities allowed in TRIPS.' South Africa, it urges, should thus avoid BITs that 'negate the gains attained in multilateral agreements such as TRIPS', and should 'encourage other developing countries' to do the same.[96]

The DTI document stresses that BITs may have different rules on anti-competitive practices, which could restrict the granting of compulsory licences. Moreover, 'where a compulsory licence is in violation of the "fair and equitable" standard of treatment, BITs protect the intellectual property that is the subject of such measures'. This can increase the amount of compensation payable, for 'TRIPS requires only the payment of adequate remuneration' based on the 'economic value of...the compulsory licence', whereas BITs take into account 'the market value of the patent'. On this basis, TRIPS allows a royalty fee that could be set at a low level (say, 3% of the price of the generic product), whereas BITS would demand 'prompt' payment of 'the fair market value' of the patent itself. Hence, 'BITs can result in a TRIPS-plus standard'. Moreover, BITS allow patent holders to take 'IP disputes to [international] arbitration', giving further unwarranted protection to patent rights.[97]

Though the draft national policy does not acknowledge this, the DTI's determination to avoid TRIPS-plus standards of protection for patents is no doubt part of the reason for the Government's decision to terminate its BITs with various European countries. Moreover, South Africa has already given notice of termination of the relevant BITs to Germany and Switzerland, both of which are home to major pharmaceutical corporations which have been much involved in the development of ARVs.

In cancelling BITs with European states and replacing them with the Investment Bill, South Africa is undermining important trade and investment relationships.

The DTI's further aim is to replace these BITs with the Investment Bill. This measure, as earlier outlined, seeks to limit the meaning of expropriation and allow the Government to avoid paying compensation for acquiring, revoking or restricting patent rights in wide-ranging circumstances. The Investment Bill will also bar foreign investors from referring disputes to international arbitration, instead obliging them to rely on South Africa's domestic courts. Once the relevant BITs have been cancelled, there will be little in law to prevent the DTI from pressing ahead with adopting the Bill. In doing so, however, South Africa will be undermining its relationship with European nations that have long been its major trading and investment partners. In addition, the DTI's attempt to give the Bill retroactive operation conflicts with the 'survival' clauses in BITs, for these normally give existing foreign investors continued protection for ten years or more after the relevant treaties have ended.[98]

CHAPTER 3
SUMMARY AND RAMIFICATIONS

The proposals in a nutshell

The proposals in the UNDP and DTI documents have implications extending far beyond the health sector. In fact, their ramifications are so wide-ranging as to make it almost impossible to foresee their full consequences. However, the clear intent in these proposals is that:

- patents will become more difficult and more time-consuming to obtain, leaving many inventions without patent protection or significantly reducing the normal 20-year period for their exclusive use;
- compulsory licences will be issued in wide-ranging circumstances, following minimal (or no) negotiations with patent holders and against royalty payments of around 3% of the price of the copies sold;
- in the health sector, compulsory licences for relevant medicines will have to be granted whenever the minister of health has gazetted a notice stating the existence of a national emergency or situation of 'extreme urgency';
- in all sectors of the economy, compulsory licences will be available for 'anti-competitive' practices that include both 'excessive' pricing and denying competitors access to 'essential facilities', as broadly interpreted by the competition authorities;
- products made under compulsory licence will not be confined to domestic markets, but will often be available for export to other countries. Export rights will apply whenever compulsory licences have been issued against 'anti-competitive' practices and perhaps also for government use. Within the health sector, export rights will also apply where importing countries face situations of emergency or extreme urgency;
- compulsory licences for 'government use' will readily be available, generally without prior negotiation and against the payment of limited royalties;
- the State may be able to acquire patents without paying any compensation for them at all, provided it does so as custodian for the disadvantaged, as the Investment Bill seeks to allow;
- BITs currently entitling foreign investors to 'prompt, adequate and effective' compensation for the direct or indirect expropriation of their patents will continue to be terminated;
- normal remedies (interim and final interdicts) for patent infringement will become difficult to obtain, while any attempt to enforce patents will invite applications for compulsory licences on all these new grounds; while
- all patent matters will be decided, not by the current patents court, but rather by a new patents tribunal freed from the need to apply the normal rules of civil procedure, which are too 'technical and legalistic'.

Normal remedies for patent infringement, in the form of interim and final interdicts (injunctions), will be more difficult to obtain.

The DTI and the UNDP document assume that changes are in keeping with the TRIPS Agreement, the Doha Declarations, and the 30 August Decision of the WTO, but this is not the case. They also assume that many positive consequences will flow from these changes: the allegedly common practice of 'evergreening' 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 yet 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 healthcare sector

The extent of the patent 'problem' within the heathcare sector is often exaggerated, while relying on generic substitutes may in practice be ill-advised. In addition, undermining patent rights will do little to overcome many other barriers to good public healthcare. 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 healthcare, limit the spread of HIV and drug-resistant TB, and make it easier for many more South Africans to buy high-quality healthcare 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. But the TAC counters that many of the medicines found on the WHO list are included because of their 'efficacy...and comparative cost-effectiveness' – which means that many innovative medicines are left off because of their price. Adds the TAC: 'If costs were no barrier, many additional medicines would be included.' 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.

Already, pressure from health activists on innovator pharmaceutical companies is reportedly encouraging them to shift their costly R&D away from TB and other diseases afflicting developing countries to focus on other illnesses. According to a recent report by *Health-e news*, Pfizer, for one, has already shifted its research focus and is concentrating its resources on a small number of areas where, a spokesman is reported as saying, it can 'deliver the greatest medical and commercial impact'. Adds Mario Raviglione, director of the Global TB Programme at the WHO: 'Pharmaceutical companies are less interested in… developing countries…as financial gain is limited. They [also] know that 95% of TB cases are in the developing world.'[99]

If the DTI's proposals are adopted – and especially if they are then replicated in other developing nations – major pharmaceutical companies will have less incentive to focus on developing new ARVs or medicines against multi-drug resistant forms of TB. Say, for example, that a major international pharmaceutical company, called XYZ for short, were to develop a new ARV which it sought to patent in South Africa. It might perhaps be denied a patent here on the new examination system proposed. If it does obtain a patent, it is likely to have to grant a number of compulsory licences to the Government, generic manufacturers, and civil society organisations claiming to act in the public interest. All these licensees would be able to sell generic copies of the ARV, both in South Africa and abroad, in return for limited royalties of, say, 3% of the price of the generic copies. Under the Investment Bill, XYZ could also see its patent taken by the Government as custodian for the disadvantaged – and without any compensation being payable to the company at all. If XYZ tried to enforce its patent rights, it would probably be denied interim and final interdicts (often the most effective remedies of all) and would invite counterclaims for even more compulsory licences.

Without secure patent rights, the pipeline of innovative medicines on which generics manufacturers depend is likely to dry up.

In these circumstances, there would be little point in XYZ seeking to patent its ARV in South Africa. But if the new ARV is not protected here, other manufacturers would immediately be able to make and sell generic copies of it here – and perhaps also in other nations confronting the AIDS pandemic. This situation might encourage XYZ (and all other major pharmaceutical companies) to concentrate on developing new medicines for use in countries where patents are better protected. Expensive R&D into medicines against the diseases afflicting the poor in South Africa and other developing countries may decline, rather than expand, as the DTI assumes.

It may also be over-optimistic to presume that the generics to be produced under compulsory licence will have the same quality as the 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'.[100]

Generics produced under compulsory licence may not have the same therapeutic quality as the original medicines, which could harm patients.

This research comes on top of other evidence that the generics drug industry in India, in particular, is falling short on quality standards. As a result, 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.[101]

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 have 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.[102]

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.[103] If India's established generics industry fails to maintain adequate standards of quality, South Africa's proposed new state pharmaceutical company – and the other new manufacturing entities the DTI hopes to see springing up (see *Ramifications for industrialisation*, below) – are likely to face similar challenges.

These considerations are not lightly to be discounted. There is also little reason to believe that undermining patents will help improve public health care in South Africa when patent rights are not the key reason for shortcomings here. Let us thus assume, for the sake of argument, that various domestic manufacturers were to start producing high-quality generics at low prices under the new rules. How much would this improve the quality and availability of public health care in South Africa? Sadly, the answer must be 'very little' – for all the other obstacles to sound health care would remain.

Other barriers to good public health care

As the Government itself has acknowledged, the quality of the public healthcare system has deteriorated sharply since 1994. Much of the decline stems from what health minister Aaron Motsoaledi has described as 'the management crisis' in public hospitals. In 2011 a competency report commissioned by him found that 'teachers, nurses, and even clerks whose highest qualification was a matric certificate' were running public hospitals, even though they lacked the experience to administer these complex institutions.[104]

Partly because of poor management, performance standards have deteriorated across a host of indicators. A recent official audit of health standards at some 3 900 public hospitals and clinics reported in 2012 that average compliance scores were:[105]

- 34% on 'improving patient safety and security';
- 50% on 'infection prevention and control';
- 50% on 'cleanliness'; and
- 54% on the 'availability of medicines and supplies'.

Some compliance scores were even worse. The availability of essential drugs in clinics was a 77% 'failure', while the score for vital health technology in maternity wards and operating theatres was a 93% 'failure' in both instances. All this, the audit added, was despite the fact that public sector health funding had increased by an average of 8.5% a year in real terms over the past five years.[106]

Stock-outs of essential medicines are becoming increasingly common. In 2012 Professor Ashraf Coovadia, a paediatrician specialist at the Rahima Moosa Mother and Child Hospital in Johannesburg, warned that drug shortages had grown steadily worse in recent years. 'Before 2011, we had good alternatives when we ran out of one drug. Now we are finding the "stock-outs" of essential drugs to be more protracted, and directly linked to the non-payment of suppliers.'[107]

State hospitals do badly on 'cleanliness' and 'infection prevention and control', while 77% of public clinics lack stocks of essential medicines.

In 2013 Section27 surveyed South Africa's state pharmacies and found that 20% had run out of drugs for AIDS or TB at various times. Mark Heywood, executive director of the organisation, said the problem was theft from government warehouses by local officials, against whom little action was being taken. Dr Motsoaledi agrees that many warehouses are sites of 'corruption and pilferage' and has vowed to act against them – but little improvement is evident.[108]

In July 2014 the National Treasury was forced to take over the financial administration of the Free State healthcare system, which had racked up R700m in debt and was on the verge of collapse. According to Section27, provincial health facilities were short of more than 200 essential drugs, including ARVs, antibiotics, pain killers, and medication for diabetes, epilepsy, and high blood pressure. This left the 2.5m people in the Free State who depended on public healthcare 'uncertain' as to what treatment they could expect.[109]

Another key problem is the acute shortage of health practitioners within the public health service. In March 2014 *The New Age* reported that public healthcare facilities face a shortfall of some 80 000 medical personnel. The situation is particularly serious in rural areas, where only 12% of the country's doctors and 19% of its nurses work. If these figures are accurate, the overall shortage is now even worse than it was two years ago, when government figures showed that vacant posts in the public health sector totalled some 44 800 for professional nurses, 10 900 for doctors, and roughly 3 500 for specialists. The cost of filling these posts was then estimated at roughly R30bn in salaries, which the Government described as 'unaffordable'. Since then, the problem of affordability has grown, for the budget deficit has risen to 4.1% of GDP, prompting the National Treasury in October 2014 to announce the withdrawal of funding for posts that have been vacant for some time.[110]

Better solutions available

Rather than undermining patent rights, the key need is to improve efficiency and quality in the public health 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 State's capacity to address, it should not seek to transfer its responsibilities to the private pharmaceutical industry but should 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 R134bn in 2014/15 and projected to rise to R165bn by 2016/17)[111] is badly used. This is largely the result of poor management, overburdened doctors, uncaring nurses, medicine stock-outs, failing equipment, inadequate maintenance, poor hygiene standards, and similar challenges. As these examples suggest (and the Government itself has acknowledged at times), much of the problem lies not in a lack of money but rather in a lack of management.

To the extent that more money for medicines is required, the Government could help meet this need by cutting back on its own corrupt and wasteful spending. How much the State loses each year to corruption is impossible to tell, but one informed estimate (by Willie Hofmeyr, then head of the Asset Forfeiture Unit, an anti-corruption entity within the National Prosecuting Authority) has put it at between R25bn and R30bn in every year.[112]

The health budget is badly used, while the Government loses billions of rands every year to corruption and wasteful spending.

Preferential procurement under the rubric of black economic empowerment (BEE) also costs the State dearly. The secretary general of the ANC, Gwede Mantashe, acknowledged this in 2012 when he said that BEE companies must 'stop using the State as their cash cow by providing poor quality goods at inflated prices'. Added Mr Mantashe: 'It is unacceptable for contractors to charge taxpayers R20m for a public school when the private sector spends between R5m and R10m on a similar project.'[113] On a state procurement bill running into hundreds of billions of rands, the cumulative waste is enormous.

The Government has the power to stamp out corruption and stop wasteful spending, if it so chooses. It also has the capacity to change its current policy and allow the establishment of many more private universities and colleges, so as to increase the supply of doctors and nurses. By improving the often appalling conditions in many public hospitals and clinics, it could also reduce the impetus for South Africa's medical practitioners to shift into the private sector and/or move abroad.

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 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 Democratic Alliance leader 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.[114]

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 1 600 or more primary care clinics it has built or upgraded since 1994.[115] 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 at least two ways, without interfering with patent rights. To begin with, the Government could remove Value Added Tax (VAT) (levied at the general rate of 14%) on all medicines sold within the private sector. Secondly, it could change the law so as to enable the private sector and civil society organisations to negotiate with pharmaceutical companies for major discounts on bulk purchases. At present, the Government itself has barred such discounts via amendments made in 2002 to the Medicines and Related Substances Act of 1965, but these rules could easily be repealed. (However, in the attempt to reduce drug prices, it must also be remembered that higher prices in the private sector help subsidise much lower prices in the public service. So great is the differential that the State sometimes pays only a tenth of the cost of the same medicine in the private sector.)[116]

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 allowing price ceilings for medicines against chronic illnesses and sanctioning a return to the risk-rating of premiums. At the same time, it could encourage individuals to buy supplementary hospital and 'gap' medical insurance, 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 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.

The Government could privatise floundering public hospitals and use the proceeds, along with tax revenues, to issue all households with annual health vouchers.

Where the health needs of the poor still cannot be met, the answer is not to undermine the patent rights of all inventors, 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).[117]

Pepfar is now shifting its contributions to poorer nations and so reducing its assistance to South Africa. This means that a million South Africans whose ARVs are currently being funded by Pepfar will in future have to be treated out of the nation's own resources.[118] 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 donor agencies rather than trying to shift the responsibility on to the shoulders of private 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.

This approach presumes that patents are the key barrier to the growth of such an industry, but 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 inventions will do little to overcome these problems. On the contrary, 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.

South Africa's experience to date with its state pharmaceutical company is also not encouraging. In 2007, at the Polokwane national conference that elected Jacob Zuma 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 a state pharmaceutical firm was also established. However, it has yet to assume operations or even to complete the construction of a pilot plant. [119]

The firm, called 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, but Lonza withdrew from the venture in 2013. Ketlaphela (a Sesotho word meaning 'I will survive') is intended to manufacture active pharmaceutical ingredients (APIs) for the production of ARVs and was initially expected to start producing APIs in 2016. However, officials now see 2017 or 2018 as more likely start dates. Comments Ryan Lobban, a healthcare analyst at Frost & Sullivan: 'Manufacturing APIs is a sophisticated business. It requires special skills. The set-up costs are very high.' Moreover, 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 producers on cost and quality if it is to persuade local pharmaceutical companies to shift away from their Asian suppliers.[120]

Yet many state-owned enterprises in South Africa – including Eskom, South African Airways, the Post Office, and the South African Broadcasting Corporation – are poorly managed and singularly inefficient, failing to discharge their mandates while frequently requiring millions of rands in bail-outs from the fiscus. 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'.[121] However, these claims are driven more by socialist ideology than by the record to date of either Ketlaphela or the country's other SOEs.

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.[122] According to the TAC, this decline shows that patents do little to encourage direct investment. As the TAC puts it, in 1997 South Africa increased the period of patent protection available here from 16 years to 20 years (as TRIPS requires), but it nevertheless 'witnessed a massive decline in pharmaceutical production and investment by R&D multinational corporations'. The only pharmaceutical companies that expanded in South Africa were the generics manufacturers, whose growth was restricted by the country's patent laws.[123]

The state-owned pharmaceutical company will battle to beat producers elsewhere on cost and quality, and could be just as inefficient as other SOEs.

However, the TAC's analysis overlooks the policy changes and *dirigiste* interventions that helped persuade innovator companies to close down their South African factories. In 2004 the ANC Government introduced price controls on medicines (using the 'single exit price' mechanism), and has since refused to allow these regulated prices to increase in line with inflation, rand weakness, and rising production costs. In addition, health activists have long been demanding that innovator companies reduce their prices still further, while the Government is planning to introduce a national health insurance scheme that could threaten the viability of both the public and private healthcare sectors.

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, South Africa's skills and productivity have remained poor, its regulatory burden is rising, and the growing inefficiency of government has become a major obstacle to business in every sphere. In these circumstances, it is hardly surprising that innovator companies have found it particularly difficult to sustain their operations in South Africa. Generics manufacturers have naturally found it easier to prosper because they do not have to pay for R&D on the medicines they produce.

South Africa has a proud record of local innovation in deep-level mining, the development of petrol from coal, and a host of other spheres.

In addition, as the UNDP article emphasises, local generics manufacturers will need to export to other countries to achieve economies of scale and bring prices down. Under the 30 August Decision, South Africa will be entitled to export ARVs and other medicines to SADC countries facing similar health problems, but this additional market is unlikely to suffice. The key factor will be the capacity to export to non-SADC countries, which the 30 August Decision will make difficult to achieve. In addition, South Africa will battle to compete with India, in particular, which has better skills and productivity, plus lower labour and other input costs.

Ramifications for the wider economy

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 is misleading when the proposals extend to patents in all spheres. The proposals are 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

Since local inventors must start by seeking a South African patent before they can apply for patents in other countries, the content of the Patents Act is vital to local innovation. The UNDP article discounts this, saying it makes sense for South Africa to 'impose reasonable limits' on the rights and remedies available to patent holders when 90% of them are foreign.[124] It is true that the proportion of local patent applications has come down sharply, from some 30% in the 1970s to some 8% in 2012, but this does not mean that the interests of local inventors can simply be overlooked. Nor does it make sense to do this when the DTI and other government departments are simultaneously seeking to stimulate local innovation in a variety of ways.

South Africa has a proud record of local innovation in deep-level mining and the development of petrol from coal. Other important South African inventions include:[125]

- Pratley Putty, a world-famous mouldable epoxy putty that was chosen by NASA as one of the adhesives used on the Ranger Moon Module Project, and which has also been used to repair a support for San Francisco's Golden Gate Bridge;
- the Kreepy Krauly, an automated swimming pool cleaner, now widely used across the world;
- Q20 lubricant, which acts as a water repellent, keeps rust at bay, oils hinges, and makes it easy to release rusted nuts and bolts;
- the Tellurometer, which revolutionised map-making because it could accurately measure long distances (of up to 50 kilometres) and was also lightweight and portable, needing little energy to function;
- 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 Cybertracker, a palm-top computer with a built-in global positioning system (GPS), which uses a series of icons to represent game species, their tracks, and other information and makes it easy for illiterate game wardens to maintain accurate records of game movements;
- the speed gun, which accurately measures the speed and angles of fast-moving objects such as cricket and tennis balls;
- 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 retinal Cryoprobe, a pencil-shaped device with a frozen tip which is important in cataract surgery and was used to treat British prime minister Margaret Thatcher in 1983 and President Nelson Mandela in 1994;
- the Smartlock safety syringe, which provides improved protection against needle-stick injury and infection with hepatitis or HIV, and has saved countless lives;
- a micro-thin metallic film, developed at the University of Johannesburg, which makes solar energy five times less expensive than earlier technologies;
- the 'Lightie' Solar Bottle light, which provides 40 hours of light after being charged with eight hours of sunlight;
- 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;
- the RoboBEAST, a 3-D printer for ordinary, non-technical people that enables them to print artificial Robohands of any size;
- various mechanised drill rigs, roof bolters, and mechanical sweepers which are currently being developed to replace human rockdrillers and improve safety and productivity on the mines;
- a ground-penetrating radar applied from within a borehole, which helps to track the location of gold and platinum reefs;
- laser-cladding technology, in which a coating is placed on a worn metal surface, allowing rotating machine parts to be refurbished locally; and
- the world's first digital laser, which was developed by South Africa's state-funded Council for Scientific and Industrial Research (CSIR) in 2013.

The DTI and other government departments are also trying hard to promote local innovation as a stimulant to industrial and economic growth.

Also important is a simple but vital device for helping to secure harbours and tame the power of the sea. This is the 'dolos' – a strangely-shaped piece of concrete, weighing up to 20 tons, which is used to protect harbour walls. This innovation has been copied around the world because it was never patented.[126]

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 declining, rather than improving, over the last four years. According to Derek Hanekom, 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 stood at 0.87% of GDP in 2009/10, at 0.92% in 2008/09, and at 0.93% in 2007/08.[127]

Overall, the country continues to lag behind the Government's goal of spending 1% of GDP on R&D in every year. Moreover, even if this target is achieved, South Africa will still be spending less than the international average of 1.77% of GDP. The country also trails behind most of its BRIC counterparts: China spent 1.84% of GDP on R&D in 2012, while Brazil spent 1.16% and Russia 1.09%. Only India comes in behind South Africa, for it spent 0.76% of GDP on R&D in 2008, the latest year for which its figures are available.[128]

The Government sees the value of patents where its 'own' R&D is in issue, and wants state-funded research institutions to patent their inventions.

According to Mr Hanekom, '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.[129]

The latter department is also trying to promote space science and technology (S&T) because it regards this as vital to 'improving the competitiveness of the country's economy and the quality of life of South Africans'. As part of this initiative, South Africa has developed a national space strategy; built an earth-observation micro satellite, SumbandilaSat (launched on a Russian Soyuz rocket in 2009); introduced a satellite engineering training programme at the Cape Peninsula University of Technology; established the South African National Space Agency (Sansa); and launched a small cube satellite, called TshepisoSat, to provide space weather data to Sansa.[130]

The current minister of science and technology, Naledi Pandor, has recently 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. Under the new requirements, the Cabinet is obliged to respond to Naci's recommendations and must give reasons if it does not. Cheryl de la Rey, vice-chancellor of the University of Pretoria and the new head of Naci, wants the council to play a larger role in stimulating innovation, saying: 'We need to take stock of where we are [as regards innovation] and identify the most urgent issues that need to be addressed, the levers that are most likely to institute the most change in the shortest period of time.'[131] Ironically, one of her most pressing tasks will be to counter the DTI's proposed changes to patent legislation, which will serve to stifle the innovation the council is intended to promote.

Ironically, the Government also recognises the value of patent protection where its 'own' R&D expenditure is at stake. This is evident, for example, in the Intellectual Property Rights From Publicly Funded Research and Development Act of 2008, which was brought into operation in 2010. This statute seeks to ensure that 'intellectual property emanating from publicly funded research and development is...protected...and commercialised', and that 'human ingenuity and creativity are acknowledged and rewarded'. It also aims to 'provide incentives' to state-funded research institutions, such as the Council for Scientific and Industrial Research, to 'reward them for proactively securing protection for intellectual property and...generally promoting innovation'.[132]

Innovation in international overview

Many developed countries have secure intellectual property rights, which help to encourage innovation and contribute to the high number of patent applications they receive each year. Comparative data on this issue is compiled annually by the World Intellectual Property Organisation (WIPO), a United Nations specialised agency dedicated to the promotion of innovation and creativity. The most recent WIPO statistics available identify the following countries (listed alphabetically) as having received the most patent applications in 2012: [133]

Name of Country	*Applications to Patent Office*		
(Listed in alphabetical order)	*Total*	*Resident*	*Non-resident*
Australia	26 358	2 627	23 731
Brazil	30 116	4 804	25 312
Canada	35 242	4 709	30 533
China	652 777	535 313	117 464
France	16 632	14 540	2092
Germany	61 340	46 620	14 720
India	43 955	9 553	34 402
Japan	342 796	287 013	55 783
Republic of Korea	188 915	148 136	40 779
Russian Federation	44 211	28 701	15 510
United Kingdom	23 235	15 370	7 865
United States of America	542 815	268 782	274 033

In 2012, for the first time, the total number of patents granted world-wide exceeded the one million mark, with 694 000 issued to residents and 439 600 to non-residents. The fastest growth was evident in Japan, the United States, and China – which, for the second time in a row, also accounted for the largest number of patent applications in the world. An estimated 8.66 million patents were in force across the globe in 2012. The United States continued to have the largest number of patents in force (2.24 million), followed by Japan (1.7 million), and China (0.9 million).[134]

Significantly, the importance of intellectual property rights was recognised by both China and Russia soon after they opened up their former command economies to the market system. China's first patent law was adopted in 1984 and came into force the following year. However, it did not cover pharmaceuticals and limited the term of patent protection to 15 years. It also had a complex and lengthy pre-grant opposition and examination system, with appeals from decisions of its patent office lying first to a 'patent re-examination board' and thereafter to 'patent administrative bureaus'. These bureaus were given the task of hearing appeals because the newly re-established court system was seen as too over-burdened and under-skilled to handle patent matters.[135]

In 2012 China received more than 650 000 patent applications and the United States some 540 000. Some 8.7m patents were in force world-wide.

China, which joined the WTO in 2001, has now improved its patent protection in various ways. It has scrapped its earlier examination system, extended protection to pharmaceutical products, and increased the term of patent protection to 20 years. China now allows the granting of preliminary injunctions and defines infringing conduct more widely. However, the patent administrative bureaus have proved difficult to eliminate and still decide on infringement matters, though subject to court review.[136]

Russia was particularly quick to introduce patent protection. The year after the Soviet Union collapsed in 1991, it adopted a Patents Act which has since been amended in various ways. The Russian patent office (Rospatent) has two key divisions, one of which receives and examines patent applications, while the other (the Chamber for Patent Disputes) handles appeals against their rejection or granting. Russia applies an examination system, in which the applicant for a patent must file a request for such examination within three years, failing which the application is deemed to have been withdrawn. Unlawful decisions by Rospatent can be challenged before the Arbitration Court and, if needs be, its appellate division. The normal patent term is 20 years from the date of filing, while the circumstances in which compulsory licences may be granted are similar to those currently contained in South Africa's Patents Act.[137]

South Africa is a minnow by comparison, for it received only 7 500 applications in 2012. However, it is also the only African state to receive a significant number of patent filings.

International data also shows the importance of patent protection in attracting or retaining the scarce skills on which innovation depends. According to WIPO statistics, the United States attracted some 117 250 immigrant inventors between 2006 and 2010, far more than any other country. Most of these skilled individuals came to it from China, India, Germany, and the United Kingdom. China and India suffered the greatest loss of inventors over this period, most of whom went to the United States. Within South East Asia, Singapore stood out for many years as a major receiving country from other nations in the region. It is only in recent years, as Chinese patent protection has strengthened, that China has begun to attract a large number of immigrant inventors from both Asia and the rest of the world.[138]

South Africa's position in the global innovation stakes

South Africa is a minnow by comparison with the countries identified above, for it received only some 7 500 patent applications in 2012. South Africa is nevertheless the only African state to have a significant number of patent filings, and compares well with many other developing countries. However, it also lags behind tiny island states such as Hong Kong and Singapore and is roughly equal to New Zealand and Israel. In addition, Israel has almost double the number of resident patent applications, pointing to a much higher level of local innovation.[139]

Name of Country	*Applications to Patent Office*		
(Listed in alphabetical order)	*Total*	*Resident*	*Non-resident*
Argentina	4 813	735	4078
Cote d'Ivoire	27	26	1
Egypt	2 211	683	1 528
Hong Kong (China)	12 988	171	12 817
Indonesia	5 838	541	5 297
Israel	6 792	1 319	5 473
Kenya	259	123	136
Madagascar	44	4	40
Malaysia	6 940	1 114	5 826
Morocco	1 040	197	843
New Zealand	7 099	1 425	5 674
Rwanda	70	40	30
Singapore	9 685	1 081	8 604
South Africa	**7 444**	**608**	**6 836**
Venezuela	1 598	33	1565
Zambia	38	7	31

Many sub-Saharan African countries, including Angola, Botswana, Burundi, Ghana, Lesotho, Mauritius, and Zimbabwe, received no patent applications at all in 2012. Various other countries – among them, Burkina Faso, Madagascar, Mali, Namibia, Nigeria, Senegal and Uganda – received patent applications via African regional organisations (the African Intellectual Property Organisation or the African Regional Intellectual Property Organisation). However, the number of patent applications received by these regional bodies in 2012 was small, at 505 and 603 respectively.[140]

Writes Jasson Urbach, a director of the Free Market Foundation:[141]

> To date, South Africa has a proud record in upholding patent rights – a record which has generally been lacking elsewhere on the African continent. This has helped it to attract a high level of foreign investment and contributed to the development of local industry. It has also helped South Africans gain access to some of the world's most advanced goods and services…
>
> Business decisions to invest in foreign countries are complex and take into account a wide variety of factors, from energy availability to…the size of domestic markets. Robust and effective patent protection is thus not enough in itself to attract FDI – but a weak patent system can act as a significant deterrent for innovative companies seeking to earn a return on their investments.
>
> Moreover, in the vast majority of countries across the globe, standards of patent and IP protection are improving. Reducing patent protection in South Africa is a short-sighted and inappropriate strategy that will further reduce the country's competitive advantages and diminish its attractiveness as a viable investment destination.

The investment climate and the rule of law

One of the most disturbing elements in the DTI's draft policy is the proposal to replace the existing patents court with a new patents tribunal, which will operate outside South Africa's high court and without being bound by the usual 'legalistic' rules of civil procedure. The administrative decisions of this tribunal will still be subject to judicial review, but the ambit of such review is generally limited. Though it covers issues of procedural fairness (*audi alteram partem*, or hear the other side, for example), on substantive matters judicial review of administrative action is limited to such questions as whether a decision was taken 'in bad faith', or 'for a reason not authorised by the empowering provision', or was 'so unreasonable that no reasonable person could have taken it'.[142]

Yet effective judicial remedies are vital to development. 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, [innovation] falters, with considerable losses to the country.'[143]

The patents tribunal could serve as a precedent for similar administrative tribunals with decision-making powers over other kinds of property.

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 patents 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% of GDP, still far behind the global norm. Perversely, the DTI's patent 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.

As Norman L Balmer, a senior patent attorney in the United States, told an International Judges' Conference on IP Law in Washington DC in 1999: 'Just as a donkey will not chase after a carrot on a stick unless he is allowed to catch it once in a while, innovators will not invest in inventing, developing, implementing, and marketing new technology unless they believe the patent promise to be real.'[144]

Adds 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.'[145]

The DTI's proposals fly in the face of this reality. They also suggest that the Government wants to cherry pick the most successful inventions for its own benefit. At present, the returns generated by successful innovations help cover the costs of unsuccessful R&D, making it worthwhile for inventors to continue risking their capital and other resources on ventures of this kind. But if the Government becomes entitled to acquire the best inventions after their value has been proven and for less than adequate compensation, why should inventors keep on with R&D?

The new patent rules are similar in this respect to the proposed rules for new oil and gas exploration and production, as currently laid down in the Mineral and Petroleum Resources Development Bill of 2013 (which has already been adopted by Parliament but still needs the president's assent to be enacted into law). In the oil industry, the major oil exploration companies need the profits from successful off-shore wells to help cover the costs of drilling the unsuccessful ones – but the Government wants the right to take up to 100% of the successful ones (20% for free and 80% at a price the State is willing to agree). Not surprisingly in these circumstances, some of the oil majors have already decided to turn away from exploring for oil off South Africa's coast.

Patent protection stimulates international trade, promotes FDI, and encourages innovation, the transfer of technology and the development of local industry.

The new patent rules are likely to generate a similar scenario. If companies fear the loss of their most valuable inventions to the State – in return for royalties generally too small to compensate for costly R&D – they will have yet more impetus to shift away from South Africa. They will then take their skills, creativity, and entrepreneurial flair elsewhere, limiting the country's growth potential and stifling the jobs that might otherwise have been created.

The Government has already assumed 'custodianship' of all private mining and water resources and re-opened a damaging land claims process which, ironically, bars black South Africans from acquiring the individual freehold ownership they were also denied under apartheid. Now patent and other intellectual property rights are also under threat. The DTI's proposals demonstrate once again South Africa's commitment to an outdated socialist ideology, which even China and Russia have long since abandoned. The proposed changes will also make it still more difficult to raise the annual growth rate above the meagre 1.9% of GDP at which it has languished on average since 2009. Yet, if South Africa's annual growth rate could be raised to 7% of GDP, the size of its economy would double in 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 technology of every kind, it is vital that the DTI should scrap these damaging proposals.

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> Innovation matters. The 20th century began when aeroplanes, motor cars, and radio were still in their infancy and people were dazzled by their novelty. It ended with spaceships, computers, mobile phones, and the Internet, along with a host of other inventions that have brought enormous benefits to millions of people across the globe.

Patents play a vital part in spurring on innovation by giving inventors the sole right to produce and sell their inventions for some 20 years. Patents also protect inventors against people who try to copy their innovations, thereby reaping an unwarranted reward from the creativity, insight, hard work, and costly research of others.

The Department of Trade and Industry (DTI) and other government departments offer various incentives to stimulate innovation, because they know its importance for investment, growth, and jobs.

Perversely, however, the DTI is now also seeking wide powers to take or bypass patent rights. It says this is necessary to bring down the price of medicines and save lives, but the changes are unlikely to achieve these goals. They will also extend far beyond the health sector, raising questions as to why they need so broad an ambit if the aim is simply to help the sick.

If translated into law, the proposals will reduce the impetus to local innovation. They will also give potential investors yet more reason to regard South Africa – in this second and more 'radical' phase of its transition – as a 'rogue' state with scant regard for property rights or the rule of law.

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South African Institute of Race Relations
The power of ideas

Friedrich Naumann STIFTUNG FÜR DIE FREIHEIT