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Patents: The Next Part of the Property Rights Grab

Having assumed 'custodianship' of mineral and water resources and re-opened the land claims process, the State is now 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 may not achieve these goals and will, in any event, extend far beyond the health sector.

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.

In this issue of *@Liberty*, Anthea Jeffery unpacks the key changes to patent law being proposed. The next issue will examine the legality of the proposals and the validity of the assumptions on which they are based. The aim is to help re-open a necessary debate which was choked off earlier this year when the health minister accused pharmaceutical companies seeking to campaign against the proposals of 'a plan for genocide'.

Patents and their purposes

The property rights protected in most countries cover not only physical property, such as land or factories, but also intellectual property in the form of patents and copyright. The patent system is particularly important and is designed to promote innovation by giving inventors who are granted patent rights a 20-year period to make and sell their 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.

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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 become available to all in time. This system brings advantages all around: 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.

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Patents are territorial rights, applying only in the countries in which they have been sought and granted. Hence, a multinational pharmaceutical corporation, for instance, must obtain a separate patent in each country in which it seeks an exclusive right to manufacture or market its medicines. In many countries, including South Africa, an inventor seeking patent protection for his innovation must begin by applying for a patent in his country of residence before seeking patents elsewhere. The content of South African patent law is thus particularly important to local inventors, as well as to foreign innovators seeking to do business here. The country's patent law must also comply with international requirements, including the 'TRIPS' Agreement of 1994.

'TRIPS' and other international agreements

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 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. This agreement sets down minimum standards for the regulation of patents and enforces these rules through the normal dispute settlement mechanisms of the WTO.

The TRIPS Agreement also authorises member states to 'provide limited exceptions to the exclusive rights conferred by a patent', provided these do not 'unreasonably conflict' with normal patent exploitation or 'unreasonably prejudice the legitimate interests' of the patent holder. However, in interpreting these exceptions or 'flexibilities', as they are generally known, 'the legitimate interests of third parties' must also be taken into account, the TRIPS Agreement says.

The TRIPS Agreement sets minimum standards for the regulation of patents, but also authorises 'limited exceptions' to patent rights.

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, developing nations have demanded clarity on their right to use the TRIPS flexibilities to limit patent protection.

In 2001 this pressure led to the adoption of the Doha Declaration. This document (which was endorsed by a conference of ministers from WTO member states) 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'. As this wording shows, the Declaration aims to strike a balance between upholding patent rights and allowing exceptions to them. The agreement expressly authorises member states to use the TRIPS flexibilities in taking measures to 'protect public health', as defined in this way.

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 (CIPC) – and 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.

In the early 2000s, health activists in the AIDS Law Project and other organisations began to blame the patent system for the high prices of ARVs.

Disputes over patents are adjudicated in a specialist court known as the Court of the Commissioner of Patents (the patents court), which follows the usual rules of civil procedure and functions in much the same way as the country's other high courts. 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 different – 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.

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, and other organisations began to criticise the patent system for keeping the prices of ARVs higher than they would be if more generic competition was permitted at an earlier stage. They also urged that the Patents Act be amended to take full advantage of the flexibilities included in the TRIPS Agreement, as reinforced by the Doha Declaration.

The DTI's Draft National Policy on Intellectual Property is poorly drafted and difficult to understand.

These views 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.

The DTI's policy proposals attracted some 115 comments, almost all critical, but the DTI is pressing ahead with enacting them into law.

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, announcing in late October 2014 that it plans to send a bill to Parliament before the end of the year. 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.

The Government's stated goals

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'; 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 aims 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 seeks to expand 'compulsory licensing' to bypass patent protections, and to limit remedies for patent holders.

The DTI/UNDP documents

In order to achieve its two main goals, the DTI, as further explained in the UNDP article, seeks to change the relevant rules in six 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 patent rights without having to pay compensation; and
- put an end to BITs that give foreign investors a 'TRIPS-plus' level of protection.

All the proposed changes are more fully described in an IRR policy paper soon to be

published. In the interim, this issue of *@Liberty* summarises some of the key changes the DTI seeks.

Making new patents harder to obtain

Under the Patents Act, the Patent Office may grant a patent over any 'new' invention which satisfies the statute's requirements for novelty and utility. South Africa is also a 'depository' or 'non-examining country', in which all patent applications made to the Patent Office are granted, provided a detailed patent specification (description of the invention) is provided and the necessary fees are paid.

The depository system has safeguards too, for it puts pressure on all applicants to ensure that no similar patent already exists.

In various other countries, by contrast, all applications are examined for novelty and utility before patents are granted. However, 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.) In addition, the validity of a patent can always be challenged – and there is arguably little difference in the cost or difficulty of doing so before or after its grant.

Both the DTI and UNDP documents nevertheless seek to end South Africa's depository system and replace it with an examination one. They claim this is necessary to stop the common practice by pharmaceutical companies of 'evergreening' or artificially 'extending' their patents over key medicines by simply developing new forms of existing substances (a syrup variety of nevirapine, for instance).

However, health activists exaggerate the extent and impact of this alleged 'evergreening'. In particular, the normal 20-year patent term cannot be extended because of an improvement later developed. Moreover, if a second patent is granted for the improved new form of an existing medicine, there is nothing to prevent the copying of the initial version once the first patent expires. But health activists disregard this, if only because they want to be able to take advantage of the 'trivial' improvements they simultaneously downplay.

In addition, South Africa lacks the skills and resources for an examination system, which even wealthy countries such as the United States battle to implement. Moreover, the new requirements would not be limited to medicines developed by multinationals but would apply to inventions of all kinds, both local and foreign.

The DTI seeks a new examination system, which it says is needed to stop the 'evergreening' or artificial 'extension' of patents over medicines.

In practice, the mooted change – and the long delays it would inevitably entail – would penalise all South African inventors. It would make it difficult for them to obtain patents within a reasonable time and 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 – could become a major barrier to local innovation.

Expanding the scope for compulsory licences

Provided patent holders see commercial advantage in such agreements, they often grant

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 firms the right to exploit patented products without the consent of the patent holder. Compulsory licences thus erode patent protections against the inventor's will.

Compulsory licences give outsiders the right to exploit patented products without the consent of the patent holder.

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 following a comprehensive hearing in the patents court. 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'. 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.

A regulatory straitjacket

According to the UNDP document, patent holders must be induced to grant many more voluntary licences by means of a new regulatory framework. These new rules should state that a compulsory licence *must* be issued if negotiations on a voluntary agreement have not succeeded within a set period of (say) 60 days, and if the patent holder rejects mooted royalty payments of (say) 3% of the price of the copied product. Moreover, any failure to meet these conditions should also 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).

The UNDP document claims that such rules would be in keeping with TRIPS, which generally requires prior negotiations, over 'a reasonable period', with the patent holder but does not stipulate the period needed. In addition, it says, TRIPS seeks only 'adequate remuneration' for the patent holder, which this new framework would allegedly provide.

The Patents Act allows compulsory licences, but solely against the 'abuse' of patent rights and as decided by the patents commissioner after a full hearing in the patents court.

Situations of 'national emergency' or 'extreme urgency'

The TRIPS Agreement adds that the requirement of prior negotiation 'may be waived by a member state in the case of a national emergency or other circumstances of extreme urgency'. In addition, the Doha Declaration gives all WTO members the right to decide for themselves when such circumstances pertain. It also recognises 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'.

According to the UNDP article, neither TRIPS nor Doha require the formal declaration of an emergency. Hence, all that is needed is for South Africa's health minister to publish a notice in the *Government Gazette* stating that a situation of national emergency or extreme urgency exists. The UNDP document urges that the Patents Act be amended to include rules of this kind. It also wants the new provisions to compel the relevant authorities to grant compulsory licences for patented ARV and other medicines whenever such notices have been gazetted.

New rules would compel the granting of compulsory licences for patented medicines whenever the health minister has proclaimed a situation of 'extreme urgency'.

Government use

Under the present Patents Act, the Government may use a patented invention solely for 'public purposes' and then only if the patent holder has agreed to this or the patents commissioner has made a ruling allowing this. The UNDP document criticises these provisions, saying they overlook another important TRIPS flexibility.

According to the TRIPs Agreement, the need for prior negotiation with the patent holder also falls away where a compulsory licence is granted for 'public non-commercial use' or, in other words, for 'government' use. Moreover, the TRIPS Agreement has few explicit guidelines as to the permissible limits of government use, so the UNDP document stresses.

The UNDP document urges that the Patents Act be changed to take advantage of this TRIPS 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 draft 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.'

General public health grounds

According to the UNDP document, the Patents Act must also be amended to include a 'catch-all' provision allowing the granting 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 '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 Government could use any patented invention without any prior negotiation, provided it pays 'adequate' royalties to the patent holder.

'Abuses' of patent rights

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

- failure to 'work' (or exploit) an invention in South Africa within a prescribed period;
- providing insufficient supply to meet demand on reasonable terms;

- refusing to grant a licence on reasonable terms, where it is 'in the public interest' to do so; and
- charging an excessive price in comparison to the price charged for the same item in other countries.

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).

A patent holder charging prices well above manufacturing costs will be deemed guilty of 'anti-competitive conduct'.

The UNDP document also wants the existing provisions expanded to include various definitions of conduct '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'.

'Anti-competitive' conduct

The TRIPS Agreement recognises that compulsory licences may be needed to counter anti-competitive practices by patent holders. It also says that prior negotiations with the patent holder are not needed in these circumstances, and that the usual restrictions on the exporting of goods made under compulsory licence do not apply. These additional flexibilities make compulsory licences against anti-competitive conduct particularly useful, as the UNDP document points out.

The TRIPS Agreement also allows member states to decide for themselves what conduct by patent-holders is 'anti-competitive'. In South Africa, the relevant rules are contained in the Competition Act of 1998, which prohibits any firm 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 where a business has a 35% share of the market and cannot disprove its market power. 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] to their customers'.

Under the new rules, any proven anti-competitive practice would also warrant the granting of a compulsory licence.

Under American anti-trust law, facilities deemed essential include infrastructure such as railway bridges, local electricity transmission networks, and sports stadiums. But the South African definition is wider, allowing a broader interpretation. This came to the fore in 2003, when the then competition commissioner, Menzi Simelane, ruled that GlaxoSmithKline and Boehringer Ingelheim were abusing their dominance by denying competitors access to an 'essential facility' – the patented formula for their AIDS drugs. An editorial in *Business Day* warned that this 'novel' ruling would undermine patent protection in South Africa, not only in the health sector but also in all other spheres.

In 2003 the competition commissioner ruled that it was 'anti-competitive' for two pharmaceutical companies to deny competitors the patented formula for their AIDS drugs.

This ruling was never confirmed by the Competition Tribunal, as the pharmaceutical companies instead settled the matter by granting seven 'voluntary' licences to firms to produce and sell generic copies of their ARVs not only in South Africa but also in all other countries in sub-Saharan Africa. The ruling nevertheless sets a precedent that could be widely invoked to justify the granting of compulsory licences against a range of patent holders.

Side-stepping export restrictions

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'. However, this TRIPS constraint does not apply where the patent holder is engaged in anti-competitive conduct. According to the UNDP document, this makes it all the more important to amend the Patents Act to authorise the granting of compulsory licences in these circumstances.

The usual constraints on exports can also be circumvented to a significant extent under the '30 August Decision' of the General Council of the WTO. This decision, adopted in 2003, waives the rule requiring predominantly domestic use if certain conditions are met. Among other things, countries that wish to import must notify the TRIPS Council that they face situations of national emergency or extreme urgency, or require particular products for government use.

However, the Decision lays down various additional requirements that must also be fulfilled. For example, importing countries must 'specify the names and expected quantities of the products' they need; while exporting ones may supply only the quantities needed, and must use special packaging, colouring, or shaping to help prevent their exports being diverted to other markets.

The UNDP document criticises these constraints. It also suggests that they need not always be upheld, but fails to explain the basis for this view. Instead, it simply asserts that South Africa should not 'make the procedures [for exporting] more cumbersome than necessary'. Adds the document: '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'.

Products made under compulsory licence may not be exported in general, but this TRIPS rule does not apply where the patent holder is engaged in anti-competitive conduct.

Limiting the remedies available to patent holders

The Patents Act allows a patent holder to enforce its rights by applying to the patents commissioner for an interdict (injunction), the delivery up of all infringing products, and damages. But 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.'

Health activists seek to protect the investments of generics manufacturers, but not the much larger investments of companies engaged in original research.

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.

The UNDP document thus urges that patent holders should be barred from obtaining interim interdicts – often the most effective remedy for alleged infringement – unless they can prove the existence of exceptional circumstances in which royalty payments would not suffice. It adds that final interdicts against proven infringements should not be granted either, if it is 'in the public interest' to deny such relief, or if the payment of damages would be 'sufficiently adequate to compensate the patent holder'. Yet, as Judge Louis Harms, a former vice president of the Supreme Court of Appeal, has commented: 'Final interdicts are [presently] granted as a matter of course in South Africa', because a failure to do so would 'amount to granting the infringer a compulsory licence'.

The UNDP article also wants the Patents Act amended to allow the defendant in any infringement proceedings to counter-claim for a compulsory licence on any of the grounds earlier outlined. This, of course, would deter patent holders from attempting to enforce their intellectual property rights.

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, for instance, would be made by an 'administrative tribunal'. Such decisions would 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 an administrative a tribunal could not be stayed (placed on hold) pending the finalisation of the review.

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'.

The DTI wants to replace the patents court with a patents tribunal, which would not be subject to high court rules with their 'highly technical and legalistic procedures'.

Increasing the scope for state acquisition

The Patents Act currently allows the minister of trade and industry to acquire 'any invention or patent' on behalf of the State, 'on such terms and conditions as may be agreed upon'. This provision limits state acquisition to instances where

agreement with the patent holder can be reached. According to the UNDP document, this is not enough to satisfy the public interest. Hence, the Act should be amended to allow the State to acquire a patent in exchange for 'just' compensation, even where the patent holder does not agree.

The State could also expropriate patents for 'just' compensation – or take them without compensation at all.

The UNDP document adds that the Government must also be able to expropriate patents 'in those rare and extreme cases in which outright expropriation would be appropriate'. This acquisition would be 'subject to compliance with Section 25, *insofar as it deals with expropriation*' (emphasis supplied).

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.

The Investment Bill

The Investment Bill applies to all property, including intellectual property, which is used 'for commercial purposes'. Some of its provisions echo the property clause in the Constitution in entitling the owner of such property to 'just and equitable compensation' in the event of expropriation. However, other clauses 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.

Actions of this kind, as listed in the Investment Bill, include:

- 'measures which result in the deprivation of property but where the State does not acquire ownership of such property', provided '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'.

Under this first provision, there would seemingly be no expropriation if the State were to take a patent for an ARV medicine as 'custodian' for the disadvantaged – and then allow various generics manufacturers to apply to it for licences to produce and sell the medicine. The constitutional validity of these provisions would also be difficult to contest when the Constitutional Court, in the *Agri SA* case in April 2003, has implicitly endorsed this approach (see *@Liberty* 3/2014 and 11/2014).

Under the Investment Bill, the State could take a patent for an ARV as 'custodian' for the disadvantaged and then allow its use by generics manufacturers, without having to pay compensation.

Under the second provision, there is also 'no act of expropriation' if the State revokes or limits a patent, provided its conduct is 'consistent with applicable international agreements'. Such agreements would include the TRIPS Agreement, the Doha Declaration, and the 30 August Decision. This wording could perhaps allow the State to restrict patent rights, in all the ways outlined above, without patent holders being able to claim indirect expropriation and a resulting entitlement to compensation.

Ending bilateral investment treaties and their 'TRIPS-plus' requirements

The UNDP document makes no mention of bilateral investment treaties (BITs), but the DTI's policy document warns against them, saying that bilateral trade agreements can 'undermine' broader agreements such as TRIPS. 'A good example', it says, 'is where certain developing countries are forced to...renounce the patent flexibilities allowed in TRIPS.'

The DTI is terminating various bilateral treaties which offer 'TRIPS-plus' protection.

The DTI document adds that BITs often have strict rules on what constitutes anti-competitive conduct, which could constrain the granting of compulsory licences. In addition, the issuing of such licences could breach the prohibitions on 'indirect' expropriation found in most BITs and so require 'prompt' payment of 'the fair market value' of the patent. (Under TRIPS, by contrast, royalty payments may perhaps be based on the value of the copy.) Hence, 'BITs can result in a TRIPS-plus standard'. In addition, BITS allow patent holders to take 'IP disputes to [international] arbitration', rather than to national courts with more understanding of government policies.

The DTI's determination to avoid TRIPS-plus standards of patent protection helps explain the Government's decision to terminate its BITs with various European countries. South Africa has already given notice of termination to Germany and Switzerland, both of which are home to major pharmaceutical corporations which have been much involved in the development of ARVs.

Ramifications of the proposals

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. But the clear intent in these proposals is that:

- patents will be 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 copied products;
- 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;

Patents will be more time-consuming to obtain, reducing the period for their exclusive use.

- products made under compulsory licence will not be confined to domestic markets, but will commonly 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 may be issued after limited negotiations with patent holders and against royalty payments of around 3% of the price of the products copied.

- compulsory licences for 'government use' will readily be available, 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'.

The DTI and the UNDP document 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, these assumptions are flawed, as the IRR's forthcoming policy paper and the next issue of *@Liberty* will outline. The proposals in the DTI/UNDP documents threaten to choke off the development of new medicines to counter the diseases common in developing countries. They are also likely to have a chilling impact on all South African inventors.

South Africa's proud history of local innovation in many spheres will be put at risk.

Given South Africa's small (and shrinking) skills base, most patent applications within the country are lodged by foreigners, many of them multinational corporations with an extensive global reach. However, close on 10% of patent applications (down from around 30% in the 1970s) come from South Africans seeking to protect their local inventions. South Africa also has a proud history of local innovation in deep-level mining, the making of petrol from coal, medical technology (the CAT scan), encryption for Internet banking, and a host of other spheres. The DTI is also anxious to promote local innovation and wants to see spending on R&D increase to 1% of gross domestic product (GDP), significantly higher than the level of 0.76% at which such expenditure now languishes.

The DTI's draft policy on intellectual property contradicts these objectives. It also contradicts the key goals of the National Development Plan (NDP): to raise the annual rate of economic growth to 5.4% of GDP and reduce the unemployment rate from 25% to 6%.

However neither growth nor jobs will increase unless South Africa starts attracting much more direct investment, both local and foreign. Perversely, these proposals nevertheless seem calculated to deter investment of this kind.

The DTI's draft policy contradicts NDP goals to raise the annual growth rate to 5.4% of GDP and slash unemployment.

If these proposals are translated into law, this will compound growing perceptions of South Africa as a rogue state with scant regard for property rights or the rule of law. Doubts as to its commitment to international agreements may also grow, for the changes proposed often go beyond the measures sanctioned in the TRIPS Agreement, the Doha Declaration, and the 30 August Decision. The proposals also threaten South Africa's relationships with the major European countries which are its primary direct investors – and which now find their bilateral agreements with South Africa being terminated and replaced with the sham protections in the Investment Bill. The proposals could also jeopardise South Africa's participation in the next Africa Growth and Opportunity Act (Agoa), due to be enacted in the United States in 2015, for the US requires the African countries that benefit from Agoa trade preferences to uphold property rights.

Critics of the proposals thus have many and sound reasons for concern. But the Government cut off a necessary debate in January 2014, when it accused pharmaceutical companies seeking to campaign against the proposals of 'a conspiracy of satanic magnitude'. Said the minister of health, Aaron Motsoaledi, when the proposed campaign came to light: 'I am not using strong words; I am using appropriate words... This is a plan for genocide.'

According to the health minister, if the proposals are defeated, South Africa will not be able to provide ARVs to the millions in need of them. 'Drugs against cancer and tuberculosis will remain too expensive to do any good.' Hence, millions of lives will be lost which might otherwise have been saved.

The pharmaceutical companies, he went on, were trying to 'prove to patients that the lack of access to medicine in South Africa has nothing to do with [patents] but everything to do with the incompetence of the Government.' This approach 'sought to make HIV-positive people revolt'. In addition, the argument that weak intellectual property rights would 'chase away investors' was aimed at all the jobless poor. 'Anyone who is unemployed, and there are millions of them, can get into this war,' said Dr Motsoaledi. Overall, pharmaceutical companies were 'putting corporate profits before health' and 'hoping to influence society to turn against the Government'.

Not surprisingly, the minister's broadside has been effective in silencing the pharmaceutical companies and most other critics. However, emotive polemic is no answer to merited concerns. The issues in the health sector are, of course, particularly difficult and require careful consideration. The next *@Liberty* will seek to advance the debate by examining the legality of the proposals, the validity of the assumptions underpinning them, and their likely ramifications in the health sector and beyond.

- by Anthea Jeffery

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