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@LIBERTY
The policy bulletin of the IRR
12 November 2014 – 15/2014

Contents

Contact details
Telephone: (011) 482-7221
e-mail: info@irr.org.za
website: www.sairr.org.za

The DTI versus TRIPS and Doha

The Department of Trade and Industry (DTI) is pushing ahead with proposals to bypass and undermine patents in the health sector and beyond (see *@Liberty*, 14/2014). The department claims that its proposals are in keeping with binding multilateral agreements on patent rights and South Africa's own Constitution. However, this claim overlooks any number of legal barriers to what the DTI proposes.

Introduction

The last issue of *@Liberty* explained the threat to patent rights in the Draft National Policy on Intellectual Property published by the Department of Trade and Industry (DTI) in September 2013 and soon, it seems, to be enacted into law. The DTI's proposals are often vague and difficult to understand, and so need to be read in the context of an article published last year by the United Nations Development Programme (UNDP).

The changes proposed will make it harder to obtain patent rights, which in itself could deter local innovation and further reduce South Africa's competitiveness. Still more serious are further proposals to:

- bypass patent rights via compulsory licensing in wide-ranging circumstances;
- limit the remedies available to patent holders;
- replace the present patents court with a new patents tribunal; and
- allow the State to use or take patent rights for little or no compensation.

The DTI and health activists assume that all these changes are in line with binding international agreements, including the Agreement on Trade-Related Aspects of Intellectual

Property Rights (TRIPS) of 1994, the Doha Declarations of 2001 (dealing with TRIPS and public health), and the 30 August [2003] Decision of the General Council of the World Trade Organisation (WTO) on the exporting of pharmaceuticals made under compulsory licence.

Many of the changes proposed are inconsistent with the clear wording of TRIPS or other WTO agreements.

However, many of the changes are in fact inconsistent with the clear wording of TRIPS or these other agreements. The idea that the State should be able to take patents as 'custodian' for the disadvantaged and without having to pay compensation may also be in breach of the property clause in South Africa's Constitution.

The legal barriers to the DTI's proposals are outlined below, and more fully set out in a policy paper on patent rights soon to be posted on the IRR website. (The ramifications of the proposals for the health sector and the wider economy are outlined in the article which follows.)

Making patents harder to obtain

The TRIPS Agreement is binding on all members of the WTO, South Africa included. It sets down minimum standards for the regulation of patent rights, but is silent on whether countries should adopt a 'depository' or 'examination' system for patent applications (see *@Liberty*, 14/2014).

There is thus no legal barrier to the examination system the DTI proposes to introduce. The real problem is a practical one, for South Africa lacks the skills for an examination system – which even countries such as the United States battle to implement.

The DTI is nevertheless forging ahead with the shift, saying it plans to appoint 20 patent examiners from April 2015. But these individuals will not be able to deal effectively with the 7 500 or so patent applications received each year, almost all of which are likely to be technically complex and difficult to evaluate. Long delays will inevitably result, which will reduce the period of patent protection (20 years from the time of filing, irrespective of when the patent is granted) and could see 'the whole patent system falling apart', as a local patent attorney has warned.

Compulsory licences

Compulsory licences are different from voluntary ones because they give outsiders the right to exploit patented products without the consent of the patent holder. South Africa's Patents Act currently allows the granting of compulsory licences: but only in limited circumstances, only at the behest of the patents court, and only in return for royalties sufficient to compensate the patent holder for his research and development (R&D).

The TRIPS Agreement allows only 'limited exceptions' to patent rights that do not 'unreasonably conflict' with normal patent protection.

By contrast, the DTI proposals would require the granting of a compulsory licence if negotiations on a voluntary agreement have not succeeded within a set period of (say) 60 days, and the patent holder has rejected mooted royalty payments of (say) 3% of the price of the copied product.

The DTI and UNDP documents claim this would be in keeping with the TRIPS Agreement. But what TRIPS says is that member states may 'provide limited exceptions to the exclusive

rights conferred by a patent', provided these exceptions do 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 proposals are too skewed against the patent holder to meet these criteria. In addition, the TRIPS Agreement states 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. This wording does not necessarily mean that royalties should be based on the price of the copied products, as the proposals seem to assume. The TRIPS clause could equally mean that royalties must be based on the full market value of the patent the licensee is being allowed to use against the patent holder's will.

Compulsory licences may not 'unreasonably prejudice' the legitimate interests of patent holders, while also taking into account the concerns of third parties.

The proposals nevertheless urge that compulsory licences, against very limited royalty payments, should be granted in additional and wide-ranging circumstances, as outlined below.

Compulsory licences in situations of national emergency or extreme urgency

Under the proposals, compulsory licences for relevant medicines would 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'. Moreover, prior negotiations would not be needed and royalty payments could again be limited to, say, 3% of the price of the generic medicines.

The TRIPS Agreement, as clarified by the Doha Declaration on public health, would allow the health minister to gazette such a notice. However, there is nothing in these documents to suggest that the granting of compulsory licences should then be made compulsory, as the DTI wants. In addition, TRIPS requirements for 'adequate remuneration' and reasonable conduct in relation to the patent holder would still apply.

Compulsory licences for government use

The proposals envisage the Government's being able to use any patented invention, including those falling outside the health sphere, after a 'fixed period of unsuccessful voluntary negotiations' and subject to 'adequate royalties'. They add that no additional compensation for expropriation would be payable to the patent holder in these circumstances, as the patent holder would still retain the ownership of its patent.

The proposals envisage the Government's being able to use any patented invention in return for limited royalties.

The TRIPS Agreement does not define 'public non-commercial use', perhaps because it sees the term as largely self-explanatory. The UNDP article suggests that any governmental use would fit within this term, but this is by no means clear. Moreover, the proposals seek to empower the Government to acquire compulsory licences over antiretroviral and other medicines and then license their use by a state pharmaceutical company charged with manufacturing generic copies for sale both in South Africa and abroad. It is doubtful whether this would count as 'non-commercial' use. Outside the health sector, any similar conduct by the State would be even more difficult to bring within the ambit of this TRIPS exception.

The competition commissioner's interpretation of the 'essential facilities' doctrine contradicts rulings in Europe, which warn against too wide a view.

Compulsory licences for anti-competitive conduct

The proposals seek to amend the Patents Act to state that any proven anti-competitive conduct will justify the issuing of a compulsory licence. Under these new rules, there would also be no 'limitations on exports and the need for prior negotiations would not apply'.

The TRIPS Agreement does indeed dispense with export constraints and the need for prior negotiations where anti-competitive conduct is in issue, but the proposals nevertheless go beyond what TRIPS allows. Under TRIPS, 'appropriate measures' to prevent the 'abuse' of patent rights must be 'consistent' with its other requirements. TRIPS also gives a narrower meaning to 'anti-competitive practices' than the proposals envisage.

As the UNDP article shows, the underlying aim is to use the competition commissioner's rulings in 2003 against GlaxoSmithKline and Boehringer Ingelheim to make findings of anti-competitive conduct against patent holders in extraordinarily wide-ranging circumstances.

In this case, brought by the Treatment Action Campaign (TAC) and others, the competition commissioner, Menzi Simelane, found that the two companies had abused their dominant position through excessive pricing and by denying competitors access to an 'essential facility' – the patented formulas for their ARVs. However, Mr Simelane's interpretation of the 'essential facilities' doctrine contradicts relevant rulings in Europe, which caution that an overly broad approach negates patent rights and undermines innovation.

Moreover, the patent holders in this case had already taken account of the 'legitimate interests of third parties' (as TRIPS requires) by reducing their ARV prices and licensing a local generics manufacturer. Despite this, they were confronted with rulings by the competition commissioner that 'unreasonably conflicted' with their patent rights and 'unreasonably prejudiced' their legitimate concerns.

The correct meaning of the TRIPS provisions was not put to the test, as the two pharmaceutical companies decided to settle the dispute to avoid more one-sided and damaging publicity. Had the matter gone to adjudication – either to South Africa's Competition Tribunal or to the WTO's dispute settlement mechanisms – Mr Simelane's rulings would probably have been overturned for inconsistency with established competition law as well as the TRIPS and Doha agreements. The TAC seems also to have acknowledged this in 2003, when it hailed the settlement reached (under which the two companies granted 'voluntary' licences to seven local manufacturers at a royalty of 5% of net sales of the generic copies) as 'going well beyond what could conceivably have been won by pursuing the prosecution of the complaint'.

The settlement reached went 'well beyond what could conceivably have been won by pursuing the complaint' any further.

Rights to export

TRIPS requires that products made under compulsory licence be 'used predominantly for the supply of the domestic market'. This does not apply where patent holders are genuinely engaged in anti-competitive conduct, but the existence of such conduct must first be properly 'determined', as TRIPS makes clear.

The 30 August Decision (made by the General Council of the WTO in 2003) allows the exporting of specified medicines, but solely in the quantities notified to the WTO – and only by countries which lack the capacity to manufacture these pharmaceuticals, yet face major health crises. The UNDP article assumes that these constraints can be overlooked and that South Africa can simply 'choose' whether to abide by them or not.

The TRIPS Agreement requires member states to ensure 'effective action' against any infringement of patent rights.

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

Limiting the remedies available to patent holders

The proposals seek to limit the remedies available to patent holders by barring them, in many instances, from obtaining either interim or final interdicts (injunctions). Yet an interim interdict – to stop sales of copied products pending a court order confirming the alleged infringement – is often the most effective remedy available to the patent holder. In addition, refusing to grant a final interdict (after infringement has been established by the patents court) 'amounts to granting the infringer a compulsory licence', notes Judge Louis Harms, a retired deputy president of the Supreme Court of Appeal. The proposals also seek to deter patent holders from enforcing their rights by entitling defendants in infringement proceedings to counterclaim for compulsory licences on all the new grounds envisaged.

However, the TRIPS Agreement requires member states to ensure 'effective action' against any infringement of intellectual property rights. It also stresses the need for 'remedies which constitute a deterrent to further infringements'. TRIPS further provides that 'the judicial authorities [in a member state] shall have the authority to order prompt and effective provisional measures'; and that such authorities 'shall have the authority to order a party to desist from an infringement'. The use of the word 'shall' is peremptory, not permissive. (As an exception, TRIPS allows royalties instead of a final interdict in the context of public non-commercial use, but only if its provisions on such use have been upheld.)

In addition, attempting to deter patent holders from enforcing their rights is contrary to a TRIPS provision stating that 'procedures' for the enforcement of intellectual property rights must be 'fair and equitable'. Penalising patent holders for trying to enforce their rights would hardly satisfy this requirement.

Replacing the patents court with a patents tribunal

The proposals seek to replace the current patents court with a new patents tribunal that would operate outside the high court system, would not be 'dominated by lawyers' and would not be subject to the 'technical and legalistic' high court rules of civil procedure.

Proposals for a new patents tribunal contradict a TRIPS provision requiring 'civil judicial procedures' in the enforcement of patent rights.

However, this contradicts another provision in the TRIPS Agreement, which states: 'Members shall make available to rights holders civil judicial procedures concerning the enforcement of any [patent] right... 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.'

Expropriation and other 'takings' by the State

The UNDP article urges that the Government be empowered to take patents in return for 'just' compensation to the patent holder. It adds that the State must also be entitled to expropriate patents in the 'rare and extreme cases' where this would be appropriate – and hints that compensation might not be payable in these instances.

There is nothing in the TRIPS Agreement to authorise the 'taking' of patents by governments in this way.

The DTI goes further, effectively proposing (under the Promotion and Protection of Investment Bill of 2013), that no compensation will be payable where the Government takes a patent as 'custodian' for the disadvantaged and then licenses its use by others. Under the Bill, the State will not acquire ownership of the patent in such circumstances and so there will no 'act of expropriation' to require the payment of compensation (see *@Liberty* 3/2014, 11/2014, and 14/2014).

However, there is nothing in the TRIPS Agreement to authorise such 'takings' of patents by member states. In addition, the relevant clause in the Investment Bill is based on the Constitutional Court ruling (in the *Agri SA* case in 2013), which said that no expropriation had occurred when the State took an unused mining right as custodian for the disadvantaged. However, an unused mining right is often an unearned windfall and thus differs from a patent over an invention, which may have required years of costly R&D to develop. This suggests that the *Agri SA* ruling may not provide sufficient judicial authority for the uncompensated taking of patents by the State (see *@Liberty* 11/2014).

The limits of the Doha documents

The proposals assume that the Doha Declaration on 'The TRIPS agreement and public health' largely negates the content of the TRIPS Agreement for all countries confronting major public health problems resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics. However, this is not so.

The Doha Declaration does, of course, state that 'the TRIPS Agreement does not and should not prevent members from taking measures to protect public health'. It also 'reaffirms the right' of WTO members to use all relevant TRIPS flexibilities 'to the full'; and adds that 'each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted'.

However, the Declaration also emphasises the importance of 'the development of new medicines'. Though it stresses a country's right to use the TRIPS flexibilities, it does not alter the wording of TRIPS or remove its many clauses requiring reasonable treatment for patent holders. In addition, the Doha ministerial conference where the document was adopted was careful to state that support for public health requires 'both access to existing medicines and the creation of new medicines'.

The Doha Declarations on public health also emphasise the importance of the 'development' and 'creation' of new medicines.

Overall, the Doha documents seek to strike a balance between upholding patent rights over medicines and allowing exceptions to them. They therefore do not authorise the widespread derogations from patent rights proposed by the DTI. In addition, they apply solely in the context of epidemics such as AIDS and cannot sanction the bypassing of patent rights outside the health sector – a factor which the DTI proposals also overlook.

Apart from the legal barriers, there are compelling economic arguments for rejecting the DTI proposals.

Apart from these legal barriers, there are many practical reasons the DTI proposals are unlikely to improve access to health care. In addition, there are compelling economic arguments against deterring the local innovation often vital to investment, growth, and jobs in an economy increasingly centred around technology. These additional reasons for rejecting the DTI proposals are summarised in the article that follows.

- by Anthea Jeffery

** Jeffery is Head of Policy Research at the IRR*

Protected Patents Protect Patients and Promote Prosperity

The Department of Trade and Industry (DTI) aims to turn patent law on its head by vastly increasing the scope for compulsory licensing and introducing an examination system for all patent applications. It claims these changes will bring down medicine prices and stimulate a local generics industry, but neither rationale is convincing. In addition, South Africa lacks the resources for an examination system. The proposals also contradict other government policies aimed at promoting innovation, and overlook far more important obstacles to good healthcare in the public service. Overall, the DTI's plan to reduce patent protection is a short-sighted strategy that will deter local innovation and further diminish South Africa's attractiveness to direct investors.

Patents and innovation

Intellectual property (IP) rights play an integral role in promoting and fostering innovation. Patent laws are particularly important because they give innovators an exclusive right to exploit their inventions for 20 years, protecting them against unauthorised copying of their products in this period. Once this 'window of opportunity' to capitalise on an invention comes to an end, the product falls into the public domain. Individuals and companies are then allowed to copy it and derive financial benefit from it.

Patents over medicines

Patents are particularly important to the multinational pharmaceutical companies largely responsible for developing antiretrovirals (ARVs) and a host of other medicines. This is because the discovery and development of a new drug is a long, complicated and expensive process that generally involves thousands of people and consumes many resources.

The average cost to research and develop every successful drug has recently been estimated at between $800m and $1bn: equivalent to between R8bn and R10bn. These figures include the costs of thousands of failed attempts. In general, for every 5 000 to 10 000 compounds that enter the research and development (R&D) pipeline, only one is likely to be successful in the end. Moreover, only three in ten new products, on average, generate revenues equal to or greater than average industry R&D costs. Against this background, patent protections are necessary to incentivise innovator companies to bring new drugs to market.

Intellectual property (IP) rights play an integral role in promoting and fostering innovation of all kinds.

In addition, no drug in practice enjoys a 20-year patent term. Typically, it 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 drugs, therefore, have an effective patent term of approximately ten years. Given the huge amount of 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.

Part of the problem is the time needed to obtain regulatory approval for the sale and use of medicines. This is a systemic issue that affects pharmaceutical patent holders in all countries,

both developed and developing. However, the problem is particularly severe in South Africa, where it can take up to five years for the Medicines Control Council to register a medicine. Again, this means that pharmaceutical companies are unlikely to benefit from the 20 years of protection to which their patents are entitled in principle.

The DTI seeks a vast increase in compulsory licensing and a patent examination system that South Africa lacks the resources to implement.

The United States seeks to counter such problems by extending patent terms for up to five years to compensate for delays in the granting of patents or in the regulatory approval process. However, the Department of Trade and Industry (DTI) in South Africa is determined not to allow a similar reform. This was made clear in the Draft National Policy on Intellectual Property (the Draft Policy) which it published in September 2013 and plans soon to enact into law (see the preceding article and *@Liberty* 14/2014).

However, the DTI's refusal to follow the US lead in sanctioning such a reform is the least worrying of its proposed policy shifts. Far more serious are its proposals to bring about a vast increase in the compulsory licensing of patented inventions and introduce a patent examination system that South Africa lacks the resources to implement.

Compulsory licensing

Compulsory licensing is a practice that allows competitors to copy patented medicines and other inventions at a fraction of the cost and without obtaining permission from the patent holder, even though the patent has not yet expired.

South Africa's Patents Act already makes provision for the granting of compulsory licences in limited circumstances: for example, if an abuse of patent rights has been proven in a court of law. However, the DTI wants to make it easy for competitors to obtain compulsory licences in wide-ranging circumstances. It also wants to limit the royalties payable to patent holders in return to, say, 3% of the price of the copied products, which will often be too little to compensate the patent holder for his costly R&D (see *@Liberty* 14/2014).

The DTI claims this proposal will help reduce drug prices and foster the development of a vibrant local pharmaceutical industry able to meet the country's need for cheap ARVs and other medicines. However, neither rationale is convincing.

The Government already substantially controls the prices of medicines through the 'single exit price' introduced in 2004.

Medicine prices

Though the Government claims a need to force down prices through compulsory licensing, it already substantially controls the prices of medicines through the 'single exit price' it introduced in 2004.

The health minister at that time, Manto Tshabalala-Msimang, initially planned to impose a blanket 50% cut in ex-factory medicine prices, as set out in the industry 'blue book' of drug prices. However, in the face of industry objections, the regulations introduced in 2004 instead stipulated that medicines could be sold only at a 'single exit price'. This was to be based on aggregate prices in the previous year and had to be the same for all customers. In addition, this single exit price could not be increased without the minister's consent.

In 2006 the minister finally approved a 5.2% increase in the single exit price, but this was not enough to compensate companies for significantly higher input costs resulting from rand weakness (most medicines are imported) and rising inflation. A further increase of 6.5% was allowed in 2008 but was again too little to compensate for higher costs.

Perversely, the single exit price bars negotiations by private sector purchasers on price discounts for bulk orders.

This pattern has persisted. In 2014, moreover, though the pricing committee appointed by the minister recommended an increase of almost 9%, health minister Dr Aaron Motsoaledi instead stipulated a 5.8% price increase as the maximum allowed. Again, this is too little to compensate for increased production costs.

Perversely, the single exit price also bars negotiations by private sector purchasers on price discounts for bulk orders. If given the opportunity, pharmaceutical companies, like most other firms, would be willing to negotiate price reductions for bulk orders. This would be a normal commercial arrangement offering mutual benefit to both parties. But the single exit price for a particular drug has to be the same for all private sector customers, regardless of the surrounding circumstances, and so prohibits any discounts to them.

A declining pharmaceutical industry

The DTI's attempt to use compulsory licensing to stimulate the growth of a generics manufacturing industry is misguided in itself. It also ignores the extent to which previous government interventions have already contributed to a significant decline in the local pharmaceutical sector.

In 2007 a study conducted on behalf of the Presidency found that 35 pharmaceutical factories in South Africa had shut down since 1994. The DTI identifies 'competition from low-cost countries', such as China and India, as a key factor in this decline, while mergers between global multinationals have clearly played a part as well. Also relevant, however, are the Government's own policy interventions in the health sector. Its price controls over medicines have been particularly damaging, an analyst at Frost & Sullivan describing them as 'disgraceful' and a major deterrent to doing business in the country.

If the DTI's Draft Policy is translated into law, the resulting abrogation of patent rights will become a further major barrier to investment in South Africa – and especially so for the innovator pharmaceutical companies whose new medicines provide the product pipeline on which all generics manufacturers depend.

In addition, undermining patent rights will do nothing to overcome the many other factors that make it difficult for South African manufacturers to compete internationally. These range from electricity shortages to poor skills and productivity, prolonged and often violent strikes, inadequate transport logistics, and high input costs of various kinds.

In 2007 a study found that 35 pharmaceutical factories in South Africa had shut down since 1994. This is partly due to the Government's own policy interventions.

Substantive examination

The DTI claims that South Africa's current 'depository' system for patent applications makes for the granting of weak and 'frivolous' patents – and allows pharmaceutical companies to 'evergreen' or artificially

The 'evergreening' allegation is unfounded, as patents cannot be extended beyond 20 years under the current rules.

extend their patents over their most profitable medicines beyond the normal 20-year term (see *@Liberty* 14/2015).

The 'evergreening' allegation

Health activists commonly accuse patent holders of making minor variations to existing drugs in order to 'extend' patent terms on an undeserved basis. However, this allegation is unfounded, as patents cannot be extended under the current rules.

A patent lasts for a maximum period of 20 years. After that time, a drug goes into the public domain and competitors are free to copy and financially benefit from the sale of the copied drug. Often, within that 20-year period, the company that holds the patent will discover a better way to make the medicine, or a new way of delivering it, or a means to reduce the pill burden, and so on. The innovator company must then file an entirely new patent application based on this new invention or process.

If the innovator company is granted a new patent on the basis of a reformulated drug, this is because the reformation is, in fact, a novel invention and meets the requirements for inventiveness. Critics of supposed 'evergreening' may claim that the new patent is simply an 'extension' of a patent on an older drug, but this is not so. There can be no 'extension' in law, as the maximum period for any one patent is 20 years. Moreover, generic companies are free to produce the older version of a drug as soon as the original patent expires.

South Africa's limited resources

South Africa lacks the technical, administrative, and financial resources for an examination system, which even developed nations find difficult to implement. Moreover, the country used to have such a system but was forced to abandon it in 1978 – when its current Patents Act was adopted – because its skills were too limited.

According to Judge Louis Harms, a former judge president of the Supreme Court of Appeal: '[South Africa] used to have an examination system, but had to abolish it 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.'

International experience shows that it takes a patent examiner approximately three days to deal with one patent application. Since roughly 7 500 patent applications are filed in South Africa each year, this suggests a need for at least 110 patent examiners. Yet the DTI seems to believe it will be able to get by with the 20 graduates it plans to appoint as patent examiners from April 2015.

South Africa used to have an examination system but had to abolish it because it never had the people to do the job. It needs specialists willing to work at government salaries.

Multinational corporations with experience of applying for patents in a large number of countries with examination systems will find it relatively easy to comply with the new rules, for they are already well versed in the procedures and have the resources to navigate the requirements. By contrast, local companies lack this experience and will require significant time and resources to get to grips with the process. The burden of the change will thus fall particularly heavily on small and medium-sized companies.

The depository system also works well in practice, which the DTI and other critics tend to overlook. Says Rowan Joseph, an intellectual property lawyer based in Cape Town: '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 undoubtedly qualify to be patented in South Africa as well. Given the fact that virtually all developed economies have examination systems and most patents registered in South Africa come from developed countries, there is little need for South Africa to duplicate the procedures in operation elsewhere.

The depository system works well in practice, which critics tend to overlook.

Moving toward a substantive search and examination system may sound like a good idea in principle but in practice it will lead to long delays, while the inevitably higher costs will frustrate the entry of local innovators. For a country such as South Africa, which suffers from a lack of both financial and human resources, a depository system is far more appropriate.

Conflicting policies

The Draft Policy also contradicts various other government policies intended to promote innovation. The Government is well aware that R&D helps stimulate industrial and economic growth, and thus has various incentive programmes to encourage this. Ironically, two of them are administered by the DTI – which is simultaneously acting against innovation via the Draft Policy – while a third is available through the Department of Science and Technology.

The latter department has also been quick to seek patents to protect its own R&D. In 2012, for example, when South African researchers at the University of Cape Town, working in collaboration with the Medicines for Malaria Venture (MMV), achieved a major breakthrough in identifying a new malaria drug candidate, they quickly patented the compound. As the minister of science and technology, Naledi Pandor, pointed out, her department had invested R25-million in the research project and wanted to reap the benefit of its expenditure.

The same thinking underpins 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'.

In other words, when the Government's 'own' money is at stake and it wants to ensure a return on its investment, it sees the value of IP rights and does the same as researchers and companies elsewhere – it seeks patents to protect its innovations.

When the Government's 'own' money is at stake and it wants returns on its investments, it seeks patents to protect its own inventions.

IP, innovation, and investment

The International Chamber of Commerce – the largest and most representative business organisation in the world – sums up the case for effective patent protection, saying: 'The protection of IP 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.'

There is also a positive and statistically significant relationship between IP rights and foreign direct investment (FDI), trade, R&D, and patent applications. Says Douglas Lippoldt, formerly a senior economist and policy analyst with the Organisation for Economic Co-operation and Development (OECD): 'A country that enhances its IP regime may attract additional knowledge-intensive product imports otherwise unavailable on the domestic market, or it may attract inflows of foreign direct investment. In either case, international technology transfer is likely to flow as a consequence.'

Patents stimulate international trade, attract FDI, and promote local industry.

A key factor in the success and rapid growth of newly industrialised countries such as Hong Kong, Taiwan, Korea and Singapore was their adoption of market-friendly policies which protected both physical property and IP rights. In the early stages of their development, they tended to adopt IP laws but not enforce them consistently. However, they soon realised that they needed to intensify IP enforcement to gain respectability among foreign governments and investors, stimulate domestic innovation, and avoid retaliatory measures by aggrieved countries and companies.

The case of Singapore is instructive. In 1960 Singapore had GDP per capita (measured in real US$ terms) of $2 530 compared to South Africa's $3 395. By 1970 Singapore's GDP per capita, at $4 857, had marginally overtaken South Africa's at $4 781. But by 2013 Singapore had GDP per capita of $36 898, whereas South Africa's GDP per capita was a paltry $5 916.

Singapore's life expectancy at birth is also now more than 20 years longer than that in South Africa – 82 years as opposed to 60. The reason Singaporeans can expect to live long and prosperous lives has much to do with its stable regulatory environment and the fact that it respects property rights, including IP rights.

Conclusion

The DTI's Draft Policy focuses on the supposed need to save lives by bringing down the price of patented and imported pharmaceuticals. However, the policy shifts it seeks will not be limited to the health sector or to foreign companies. Instead, they will extend to inventions of every kind. They will also bear most heavily on local inventors, rather than multinational corporations.

Within the health sector, the charge that patents act as a major barrier to access to medicines diverts attention from far more important obstacles to good health care. These include poor management in many public hospitals and clinics, where even such basics as adequate hygiene are frequently neglected.

Focusing on patents diverts attention from more important obstacles to good health care.

In addition, some 98% of the drugs contained on a list of essential medicines compiled by the World Health Organization (WHO) are already off-patent. The Government should thus focus on ensuring the availability and adequate use of these medicines in the public healthcare service, where drug stock-outs are increasingly common.

Another simple reform – which would further increase access to essential medicines through a simple stroke of the legislative pen – would be to remove Value Added Tax

(VAT) on all pharmaceutical products. South Africa has already eliminated import tariffs on medicines, which has helped to contain costs. But it continues to levy VAT (at the standard rate of 14%) on all pharmaceutical products sold in the private sector, even though this makes prices higher than they would otherwise be.

Another simple reform would be to remove VAT from all medicines sold in the private sector.

Charging VAT on medicines is counterproductive. If the Government wants to promote access to health care, it should not impose this tax on people who are often the most vulnerable members of society. Taxes on medicines are highly regressive and severely penalise the marginalised. Removing VAT on medicines would be politically popular and easy to achieve.

The DTI's proposals overlook these vital issues. If carried into law, they will also penalise innovative pharmaceutical companies by denying them an adequate return on their substantial R&D investments. Yet without R&D into innovative medicines, generics manufacturers would soon have little new material to copy. This would have dire consequences for all South Africans, regardless of their socio-economic status.

Within the wider economy, each and every individual or company that may want to capitalise on inventions needs effective patent protection. This is also an essential prerequisite to attract innovative companies to invest within the country.

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, allowing all of us to become wealthier and healthier.

Business decisions to invest in foreign countries are complex and take into account a wide variety of factors, from energy availability and labour laws to the independence of the judiciary and the size of domestic markets. Robust and effective patent protection is thus not enough in itself to attract FDI – but a weak patent regime can act as a significant deterrent for innovative companies seeking to earn a return on their investments.

Reducing patent protection in South Africa is a short-sighted and inappropriate strategy.

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.

Jasson Urbach

**Urbach is a director of the Free Market Foundation*