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Draft Intellectual Property Policy of the Republic of South Africa – Phase 1

Free Market Foundation

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About the Free Market Foundation

The Free Market Foundation (FMF) is an independent public benefit organisation founded in 1975 to promote and foster an open society, the rule of law, personal liberty, and economic and press freedom as fundamental components of its advocacy of human rights and democracy based on classical liberal principles.

The FMF is South Africa's leading property rights champion. Throughout its forty-two-year history, it has fought more resolutely and consistently than any other role-player for the unambiguous recognition and protection of property rights for all South Africans. The FMF has consistently pointed out that the essence of apartheid policy was the violation of property rights. Apartheid could not have been possible if property rights had not been violated. Unlike other anti-apartheid organisations, the FMF encouraged whites to abandon apartheid policies because the violation of some people's rights, violates all people's rights.

Introduction

The Free Market Foundation welcomes the opportunity to comment on the Department of Trade and Industry's, "*Draft Intellectual Property Policy of the Republic of South Africa – Phase 1"* (the Draft IP Policy). The Draft IP Policy has been many years in the making and there has been much speculation over the course that it would take.

We were pleased to see the following acknowledgement by the Department of Trade Industry (DTI), "Intellectual Property (IP) is an important policy instrument in promoting innovation, technology transfer, research and development (R&D), creative expression, consumer protection, industrial development and more broadly, economic growth".[1]

Indeed, the International Chamber of Commerce states, "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, and its concomitant benefits for public health".[2]

For most of human history life was nasty, brutish and short. If you wanted something from your 'neighbour' you simply took it – often with force. There were no laws to protect the fruits of one's labour or any property that one had acquired. In this world people constantly lived in fear that they would be dispossessed of their property. Under these circumstances a significant amount of time and resources was dedicated to the protection of one's property. But this occurred to the detriment of other more productive economic activities.

Over time people developed laws to protect one's property that they had acquired in a legal manner. These laws allowed individuals to engage in other economic activities and to make better use of scare resources. People were then free to engage in mutually beneficial trade agreements. Recognising the importance of property rights for the advancement and prosperity of a civilised society, the Free Market Foundation (FMF) was instrumental in advocating for the inclusion of a property rights clause – including the protection of intellectual property – in South Africa's Constitution.

According to World Intellectual Property Organization (WIPO), "Intellectual property rights are like any other property right. They allow creators, or owners, of patents, trademarks or copyrighted works to benefit from their own work or investment in a creation. These rights are outlined in Article 27 of the Universal Declaration of Human Rights, which provides for the right to benefit from the protection of moral and material interests resulting from authorship of scientific, literary or artistic productions".[3]

Furthermore, WIPO states that there are several compelling reasons to promote and protect intellectual property: "First, the progress and well-being of humanity rest on its capacity to create and invent new works in the areas of technology and culture. Second, the legal protection of new creations encourages the commitment of additional resources for further innovation. Third, the promotions and protection of intellectual property spurs economic growth, creates new jobs and industries, and enhances the quality and enjoyment of life".[4]

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1 Department of Trade and Industry (2017) Draft Intellectual Property Policy of the Republic of South Africa Phase 1 2017

2 International Chamber of Commerce (2007) Intellectual Property and Medical Innovation, Submission to the Second Web-based Hearing on Public Health, Innovation and Intellectual Property of the World Health Organization

3 World Intellectual Property Organization, What is Intellectual Property? WIPO Publication No. 450(E) Available at: http://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf

4 World Intellectual Property Organization, What is Intellectual Property? WIPO Publication No. 450(E) Available at: http://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf

It is ironic that in modern times the principal criticism of patents, and the main reason for wanting to curtail them, is the concern that they deny the public access to pharmaceuticals. It is ironic because the word "patent" is derived from the Latin *patens* meaning "open". To patent something, *patentere*, meant to lay it open, to expose it. Patent laws were a means of making innovations open and available. Prior to patent laws, innovation and creativity was clouded in great secrecy. The way for people to benefit from their creative endeavour was to keep the fruits of their creativity away from the public, for fear that others would "steal" it.

Patent laws were developed to encourage people to share their inventions with others for the benefit of all. The logic was obvious: if people could own the right to their creative endeavours they would earn more by sharing them with others rather than by concealing them. Innovations would spread more rapidly to the benefit of society. Perceptive entrepreneurs would recognise their potential and develop them further. As competition builds up, it would encourage more and more people to invest in innovation.

For a country such as South Africa that aspires to reduce poverty and boost income levels, innovation is a critical cornerstone for economic growth. Innovators and creators need to be able to secure their investment in developing their creations — or, they simply do not create. They certainly will not invest in commercialising and bringing products to market if they can easily be appropriated and copied.

Intellectual property laws are only one factor among several that influence innovation. Successful implementation of intellectual property rights (IPRs) depend on complementary factors such as the quality of legal institutions, markets and infrastructure. Simply put, the efficacy of intellectual property reform is ultimately subject to the environment in which IPRs operate. National prosperity is achieved when countries implement a policy paradigm – of which an important component are IPRs.

A robust IPRs regime is thus required for any and every company that may want to capitalise on ideas – not only those in the pharmaceutical industry. IPRs protection is an essential prerequisite to attract any innovative companies to invest in SA and poor enforcement, or the lack of IPRs protection, will discourage them from doing so. Without investment from innovative pharmaceutical companies, a lack of innovator medicines would soon develop in this country which, in turn, would lead to a stagnant generic drug market. This would have dire consequences for all South Africans, regardless of their socio-economic status.

"As many have warned in the past, freedom is unlikely to be lost all at once and openly. It is far more likely to be eroded away, bit by bit, amid glittering promises and expressions of noble ideals"

Thomas Sowell: The Quest for Cosmic Justice

The problem with the problem statement

The problem statement is premised on the idea that patents act as a major barrier to access to medicines. The Draft IP Policy states, "… the intersection of IP and public health has long been an issue of contention within South Africa, and one without resolution to date… As both a constitutionally guaranteed right, as well as a key development goal, the issue of access to health care services – and the role of IP in delivering public health – has been at the forefront of human rights debates in the country". Putting aside the fact that the Draft IP Policy overlooks other constitutionally mandated rights to make its case, the Draft IP Policy fails to provide substantive evidence to support the assertion that patents are the cause of South Africa's poor healthcare outcomes.

Moreover, while the Draft IP Policy[5] does have a problem statement, it is evident that no socioeconomic impact assessment (SEIA) was conducted, or perhaps has been conducted but not released to the public, in support of the policy. The problem statement attempts to explain the reasoning behind the adoption of the policy, but this is redundant without the facts and evidence that a properly-conducted SEIA would contain. Indeed, despite the problem statement, the question lingers: Why is this policy being pursued and will the suggested remedies address "the problem"?

For the people to have a say in the decisions that affect their lives, they must know how the decision was arrived at, and on what basis, and their participation must be meaningful (in other words, government must engage in good faith) and not merely a façade. Without a SEIA, the public cannot participate in the policy-making and law-making process as mandated by the Constitution.

Without published SEIAs, government is called upon to *judge for itself* whether its *own* policies are reasonable, and this would make the Rule of Law a redundant concept. The incumbent Anton Mostert Chair of Intellectual Property Law, Prof Sadulla Karjiker, states, "Law aims to provide the necessary certainty, or predictability, by which persons can organise their affairs. In the absence of legal rules, disputes will be determined by those who have authority, according to their own ethical, or political, preferences. If there is no requirement that disputes be settled according to legal rules or principles, there would be no need for lawyers, or, indeed, the law. Disputes would simply be settled by ethicists, or politicians, most probably, the latter, as they would have the authority to impose their will on others".[6] What Prof Karjiker was essentially alluding to is the supremacy of the Rule of Law.

The supremacy of the Rule of Law

The Rule of Law is a principle of South African constitutional law found in section 1(c) of the Constitution.[7] It provides that South Africa is a democratic state founded on the supremacy of the Constitution *and* the Rule of Law. The most important tenet of the Rule of Law is its prohibition on arbitrariness. Arbitrariness is not only a symptom of unfair and bad governance, but is also very harmful to the economy, as it leads to uncertainty and means people and businesses cannot plan their affairs ahead of time.

The opposite of arbitrariness is reasonableness. Reasonableness consists of two elements, namely, rationality and proportionality. Proportionality means that there must not be an imbalance between the adverse consequences of a policy and the beneficial consequences.[8] Rationality means that evidence must support the policy. Stated differently, there must be a rational connection between the purpose of the policy and the solutions proposed.[9] It has also been said that a third element, effectiveness, is a part of reasonableness.

It stands to reason that the requirement of rationality, read together with section 195(1)(g) of the Constitution, which states the principles according to which the public administration must function, provides that transparency "must be fostered by providing the public with timely, accessible and accurate information", requires that policy or legislative interventions must be supported by demonstrable evidence.

To determine whether a policy will have the consequence intended by the enacting authority, a SEIA must be done as a matter of course, and must be publicly available to satisfy the principle of transparency. If a SEIA is not conducted, it means the intervention is not supported by evidence, and is therefore irrational and

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5 Department of Trade and Industry. "Draft Intellectual Property Policy of the Republic of South Africa: Phase I". (2017). Henceforth "the policy".

6 Prof Sadulla Karjiker (2017) IP: Politics and Beyond. Inaugural lecture

7 Constitution of the Republic of South Africa, 1996. Henceforth "the Constitution".

8 Hoexter, C. *Administrative Law in South Africa*. (2012). 344.

9 Hoexter 340.

unconstitutional, and if a study is not released to the public, government is failing to comply with section 195(1)(g), and thus, the process is unconstitutional.

In *Principles of Good Law*, the Good Law Project writes:[10]

"Although widely divergent, all the international assessment models amount ultimately to institutionalised procedures for determining the need for a law and its expected benefits. They are also concerned with the cost to government of implementation, as well as the capacity of government to police and enforce the law and the cost to the public of compliance. Other aspects considered are the economic and other likely impacts, the prospect of unexpected or unintended consequences; and the behaviour modifications likely to be promoted by the law and distortions that might flow from them."

It goes on to describe what a SEIA would encompass:[11]

"2. **Socio Economic Impact Assessment** (SEIA). Multi-faceted analysis *and quantification* of:

2.1 The purposes of laws – precisely what "mischief" they are addressing;

2.2 Desired consequences;

2.3 Estimated secondary and unintended effects, including impacts on the economy or society in general;

2.4 Feasibility and efficacy – prospects in practice of the law being observed, and if not, enforced by officialdom, police and the courts;

2.5 Costs and benefits – accurate and comprehensive estimates of costs of administration and implementation, enforcement and policing, compliance and avoidance/evasion/resistance;

2.6 Inter-departmental considerations – the extent to which other departments are implicated;

2.7 Administration and budget – advance provision for all budgetary, staffing, training and related needs; diversion or dilution of resources and capacity."

The Department of Planning, Monitoring and Evaluations' (DPME) SEIA System (SEIAS) guidelines describe the purpose of SEIA as follows:[12]

"**3. The role of SEIAs**

SEIAs aims:

- To minimise unintended consequences from policy initiatives, regulations and legislation, including unnecessary costs from implementation and compliance as well as from unanticipated outcomes.

- To anticipate implementation risks and encourage measures to mitigate them."

[10] Good Law Project 34.
[11] Good Law Project 35.
[12] Department of Planning, Monitoring and Evaluation. "Socio-Economic Impact Assessment System (SEIAS): Guidelines." (2015). 4.

The DPME regards a SEIA as more than a mere cost-benefit analysis. SEIAs, instead, must contribute to improving policy, rather than measuring their net value. It must, furthermore, "help decision makers to understand and balance" the impact of policy on different groups within society.[13]

That regulations or legislation can lead to unintended consequences is acknowledged by government. It may happen because of inefficiency, excessive compliance costs, overestimation of the benefits associated with the regulation, or an underestimation of the risks involved with following through with the regulation.[14]

The SEIA System applies to legislation and regulations, as well as policy proposals.[15]

Neither the SEIA System requirements nor the Good Law Project's guidelines have been adhered to in the Draft IP Policy.

Is a substantive search and examination system appropriate for SA?

The Draft IP Policy states "A substantial part of the problem with optimising the role of IP in the public health is that South Africa does not conduct substantive search and examination (SSE) prior to the grant of patents". As noted previously, "the problem" has not itself been adequately defined so its difficult to know what mischief the Draft IP Policy seeks to address. Nevertheless, in the absence of a SEIA, it's not clear whether a substantive search and examination (SSE) system for patent applications will have the desired effect of addressing the perceived problem and thus the proposed remedy may in fact do more harm than good. Indeed, as Prof Karjiker states, "When a policy document utilises unsubstantiated claims it leaves one with a distinct concern that it is not the product of a deliberative, evidence-based exercise, but is simply meant to provide a veneer of formal validity, or justification, to implement a particular course of action for political convenience".[16]

The DTI regards this shift from the current depository system necessary if it is to grant more robust patents. A criticism of the existing so-called "depository system" long put forward has been that it encourages frivolous patents and allows weak patents to be issued without any substantial evidence to support this claim. The Draft IP Policy references a single study to support its argument that South Africa grants patents at a much higher rate than other countries. The Draft IP Policy states, "A recent comparative study conducted by scholars from Columbia and Harvard Universities reveals that South Africa grants a far higher percentage of patents from all applications filed in the country than virtually any other comparable country".[17] But the focus of the single study cited was not South Africa's depository system but rather on a very narrow subset of countries issuing so-called "secondary patents". In fact, South Africa wasn't even included in the final regression analysis in the cited study.

Nevertheless, it should be noted that a move toward a substantive search and examination (SSE) system is supported in principle. However, there are several significant practical hurdles that would need to be overcome for this to happen. A major constraint is the lack of skilled professionals who possess the necessary capabilities to handle a more intensive and extensive system. Louis Harms, retired judge and now professor of intellectual property law at the University of Pretoria, doubts that an SSE system would work in South Africa. He states, "[South Africa] had an examination system in 1952, but had to abolish it in 1978 because we never

13 DPME 7.
14 DPME 4.
15 DPME 8.
16 Prof Sadulla Karjiker (2017) IP: Politics and Beyond. Inaugural lecture
17 Draft IP Policy (2017) pg. 7

had people to do [the job]. It's highly specialised. You need a scientist and a lawyer who will do the job at a government salary".[18]

As Harms implies, South Africa lacks the necessary financial resources. Without the required skills (both technical and administrative) and financial resources to administer this system, significant delays in the process will be likely, which will discourage future potential investment in the country. Given that virtually all developed economies have examination systems and most patents registered in South Africa come from developed countries, it would be an unnecessary and uneconomical use of resources to duplicate these efforts.

Rowan Joseph, intellectual property lawyer at Cape Town-based Von Seidels Attorneys, suggests that, because South Africa's patent laws are based on those that apply in the United Kingdom, we should get similar results. Joseph states, "The absence of patent examination in SA sounds bizarre, but it actually works because the examination is the same throughout the world".[19]

Based on international standards, it takes an experienced examiner approximately three days to process a single patent application. About 9,000 patents are filed in South Africa every year, which suggests that we would require at least 100 experienced examiners to accommodate the new system. The government, though, is currently *training* 20 examiners to effect the transition to the SSE system. The Draft IP Policy recognises the capacity constraints. The Draft IP Policy states, "In principle, therefore, patent applications should always be subjected to substantive examination. In practice, however, countries may not yet have the human and/or financial resources to put into place and properly implement a full system of substantive examination".[20] To overcome these, it is suggested that the SSE system should be phased in and limited to "certain strategic fields" that are initially targeted for full SSE. This, however, is clearly discriminatory and fails the test of general applicability, rationality and fairness.

The Draft IP Policy states that one of the goals of the IP Policy is to "… consider the development dynamics of South Africa and improve how IP supports small institutions and vulnerable individuals in society, including in the domain of public health".[21] However, moving toward an expensive SSE type system will adversely affect small institutions and will have the perverse effect of restricting access to medicines.

Large companies elsewhere are, generally, well versed with SSE type systems since most advanced countries have adopted them, and have the resources to navigate through the process. In contrast, South African companies are not familiar with the process and will require a significant amount of time and resources to "learn" the process. This will be particularly difficult for small and medium sized South African companies that may well not have the time and resources to do so.

With the current depository system and using a patent attorney, it costs as little as R20,000 to file a patent at the Companies and Intellectual Property Commission (CIPC). Contrary to the assertion that the current depository system encourages frivolous patenting, patent lawyers in South Africa undertake a significant amount of research when preparing to file a patent application with the courts.

Patent attorney at Adams and Adams, Alexis Apostolidis, states, "Very importantly, and what has gone largely unnoticed by detractors of the depository system is that patents that have corresponding applications

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[18] Makholwa, A. (2013) Pharma Dynamics' costly patent war with Bayer, Financial Mail. Accessed 23-10-2014. Available at: http://www.financialmail.co.za/features/2013/09/12/pharma-dynamics-costly-patent-war-with-bayer

[19] Makholwa, A. (2013) Pharma Dynamics' costly patent war with Bayer, Financial Mail. Accessed 23-10-2014. Available at: http://www.financialmail.co.za/features/2013/09/12/pharma-dynamics-costly-patent-war-with-bayer

[20] Draft IP Policy, pg. 15

[21] Department of Trade and Industry (2017) Draft Intellectual Property Policy of the Republic of South Africa Phase 1 2017

internationally are often voluntarily amended to be in line with the patents as examined in other jurisdictions, especially because one or more invalid claims in a patent will render it unenforceable until such invalidity is remedied".[22]

With the proposed new SSE system, we can be sure that the fees associated with filing patents with the CIPC will escalate to accommodate the increased number of staff required. The costs for patents relating to complex subject matter could easily increase by R30,000 to R60,000, depending on the extent and number of interactions with the CIPC examiner. Large companies may well be able to absorb these costs, but small, upcoming enterprises will not. A local individual will probably not be able to afford to file a patent.

Moving toward an SSE system may sound like a good idea. Higher costs and long delays caused by a woefully inadequate number of CIPC staff to handle the increased complexity associated with a SSE system will be the unavoidable, foreseeable result and will frustrate the entry of local innovators. For a country such as South Africa that suffers from a lack of both financial and human resources, a depository system is far more appropriate.

Patent opposition

The Draft IP Policy aims to make provision for: "It is recommended that, eventually, opposition proceedings are enacted in the law both prior to and after the grant of a patent. In the interim, owing to capacity constraints, it is recommended that patent law recognises a third-party submission system or "observation" to stand in for the pre-grant opposition process and for existing provisions in administrative law to be used in lieu of post grant oppositions".[23] It can be reasonably anticipated that such a pre-grant opposition system will invite frivolous opposition and will only serve to further delay the entry of innovative products onto the market. It's also not clear from the Draft IP Policy who would be responsible for adjudicating such an intervention and provisions would have to be made for review and/or appeal process which will simply serve to exacerbate the delays and costs associated with registering a patent.

The Draft IP Policy states, "A post-grant opposition mechanism that would require the development and promulgation of regulations, and makes provision – for as long as the contemplated system of post-grant opposition is not yet in force – for all such oppositions to proceed by way of administrative review in accordance with the provisions of the Promotion of Administrative Justice Act 3 of 2000 ("PAJA")".[24] Prof Karjiker states, "Administrative review proceedings are very limited forms of legal oversight: they have to be brought within the strict time limits prescribed, and are concerned with the reasonableness of decisions, not the correctness of those decisions. Thus, an administrative review is, strictly speaking, not able to resolve the issue of whether a patent should [have] been granted on the substantive basis of patent law. I am afraid that you would struggle to find many worse examples of proposed legal reform than this cack-handed proposal. This, once again, displays the concerns which I have concerning the level of legal expertise employed by the DTI when formulating proposals. If there really is a substantial problem with our depository system, the proposal will exacerbate the problem, and not provide a solution to it".[25]

Patentability criteria

The Draft IP Policy states, "In line with emerging international best practice, patentability criteria will be developed in order to promote genuine innovation through the patent system in South Africa. Such criteria

[22] Private correspondence
[23] Draft IP Policy, pg. 16
[24] Draft IP Policy, pg. 17
[25] Prof Sadulla Karjiker (2017) IP: Politics and Beyond. Inaugural lecture, pg. 10

will be implemented in the process of examination of patent applications and will aim to strike the optimal level of IP protection, promote innovation, and balance the rights of IP holders and users alike. It is recommended that patentability criteria form a part of the Patents Act, as well as any subsequent regulations and guidelines for the examination of applications".[26]

However, the current patentability criteria as set out in the Patents Act are compliant with TRIPS Article 27 and are also in line with international best practice. The FMF is thus opposed to any changes to the current patentability criteria as provided for in Section 25 of the Patents Act. The Draft IP Policy states that "patentability criteria will be developed in order to promote genuine innovation through the patent system".[27] This statement intimates that currently there are innovations in South Africa that are not "genuine" and that is simply absurd. If the South African patent register has non-genuine patents why has there not been a significant number of cases challenging the validity of those patents?

Critics of the patent system often argue that incremental improvements should not receive patent protection. This argument is as tiresome as it is wrong, since patents cannot be extended under the current laws. A patent lasts for a maximum 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. If, within that 20-year period, as often happens, the company holding the patent, discovers a new way to make the medicine, or to deliver it, or to reduce the pill burden, it then must file for an *entirely new* patent application based on the new invention or process.

If the innovator company is granted a new patent on the basis of a reformulated drug, this is solely because the reformation is, in fact, a novel invention and meets the requirements for inventiveness as adjudicated in a South African court of law. Those who believe that patents can be "extended" may claim that the new patent is simply an 'extension' of a patent on an older drug, but this is not so. As soon as the original patent expires, generic companies are free to produce the older version of a drug. And if the 'incremental' improvement did not represent a genuine innovation then why make a fuss? Obviously, for both commercial and patient welfare reasons, the newer version of the drug is valuable and represents and improvement on the original version of the drug.

Voluntary licences

The Draft IP Policy correctly points out that "Knowledge, innovation and technology are increasingly becoming the drivers of progress, growth and wealth. Therefore, South Africa needs to transition towards a knowledge economy, and away from over-reliance on natural resources. A specific framework of conditions is necessary to enable South Africa to make this transition, and an IP Policy is one of the core elements required to achieve this objective".[28]

For science, technology and innovation to drive economic growth, SA requires a strong respect for IP rights. Innovators need assurance that their ideas, once registered with the Companies and Intellectual Property Commission (CIPC) and disclosed to be capitalised upon, will receive adequate protection. Predictable laws and institutions that attract and encourage investment are fundamental to economic growth and job creation.

SA urgently needs to contribute to finding new innovative solutions to combat various diseases prevalent in Africa. Professor Kelly Chibale of the University of Cape Town (UCT)'s Drug Discovery and Development Centre (H3D) states, "Existing unmet medical needs require innovative solutions and the necessary research and development is expensive. Based on recent estimates, on average one new drug could take up to $2.5 billion

[26] Draft IP Policy, pg. 18
[27] Draft IP Policy, pg.18
[28] Draft IP Policy, pg.3

to discover and develop and represents anything up to 10,000 false starts. Someone has to pay for these costly failures along the way to one success".[29]

The Draft IP Policy states, "Notwithstanding the important role of voluntary licences, they have not always provided the requisite level of access in disease areas other than HIV/AIDS and, to a lesser extent, Hepatitis C (HCV). Therefore, while voluntary arrangements have been, and will continue to be, the first port of call, South Africa requires a broader set of policy options to address instances where voluntary mechanisms prove insufficient or inadequate".[30] The FMF welcomes the statement that voluntary arrangements will continue to be the first port of call. However, the nature of choice begets a respect for a decision made. Indeed, it cannot be said that one has a 'choice' but then the option they have chosen is deemed invalid and consequently voided. There is no choice if any of the available options are invalid.

It is thus worrying that government writes in the policy that voluntary mechanisms have proved "insufficient or inadequate". These mechanisms cannot be regarded as voluntary if the voluntary conclusion reached is deemed inadequate and thus replaced by a compulsory conclusion.

Compulsory licences

The Draft IP Policy does not provide any rationale for the expansion of compulsory licencing, other than government apparently believes "essential goods" are unaffordable and that "anti-competitive practices" require more restraining. These reasons are mentioned without elaboration. Therefore, it is clear from the language of the Draft IP Policy that government does not, in fact, agree with South Africa's voluntary licencing system. This negation of choice will introduce unprecedented uncertainty into South Africa's patent regime and should be abandoned.

International agreements

The Draft IP Policy repeatedly refers to international agreements such as the TRIPS Agreement and the Doha Declaration which condone compulsory licencing as a last resort in exceptional circumstances. While South Africa is constitutionally-bound by international law which is enacted by Parliament, any international agreement which obliges government to act unconstitutionally, cannot bind South Africa. Section 231 provides that international agreements become law in South Africa if so enacted by national legislation. Section 1(c) and section 2 of the Constitution, however, provide that the Constitution and the Rule of Law are the supreme law in South Africa and that any law or conduct inconsistent with it is void in this country.

Property rights and their limitation

There is no objection to the permissibility of compulsory licencing. Such compulsory licencing, however, is expropriation, and an unequivocal limitation of property rights. In this light, any such expropriation must accord with section 25 and section 36 of the Constitution, and not merely the broad permissive language found in international agreements.

Section 25(1) of the Constitution provides that no one "may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property". It goes on in section 25(2) to allow expropriation in the public interest or for a public purpose, subject to compensation. Section 25(4)(b)

[29] Prof Kelly Chibale (2017). Economic and health impact of intellectual property rights on pharmaceutical research and development. Available at: https://www.youtube.com/watch?v=JJwDUceU6pc

[30] Draft IP Policy, pg. 23

establishes that property is not limited to land, meaning intellectual property is similarly protected by the Constitution as other forms of tangible property are.

The policy proposes moving away from a system of negotiation, whereby government need no longer be subjected to a requirement of negotiation to acquire a licence for patents. This system is currently mandated by section 4 of the Patents Act, which provides that government may "use an invention for public purposes on such conditions as may be agreed upon with the patentee".

The policy uses government's section 27 constitutional obligation to progressively realise South Africans' right to healthcare as justification for this. However, this is as much a section 25 property rights issue as it is a healthcare issue, given that patents are protected as intellectual property under the Constitution, and thus any derogation of this property right must be in accordance with section 36 of the Constitution.

Section 36 of the Constitution provides for the limitation of rights in the Bill of Rights. Any limitation:

Must be a law of general application;

Must be reasonable and justifiable in an open and democratic society;

Must consider the values of human dignity, equality, and freedom;

Must consider the nature of the right being limited;

Must consider the purpose of the limitation proposed;

Must consider the nature and extent of the limitation;

Must consider the relationship between the limitation and its purpose; and

Cannot be justified if there are less restrictive means to achieve the purpose.

One of the considerations a court must bear in mind in when determining whether a limitation of rights is justified, thus, is whether there were any less restrictive means for government to achieve its end. Since government has hereinto been subjected to a requirement of negotiation prior to the expropriation of patents, a court will conclude that negotiation is a less restrictive means than jumping directly to expropriation.

It must thus conclude that this limitation of property rights is unconstitutional. The policy must be amended to reflect this reality and re-commit South Africa to the system of negotiation. Indeed, the research cited in an article published in the journal *Health Affairs* demonstrates that negotiation and collaboration on mutually beneficial terms provides better returns than what can generally be achieved by issuing compulsory licences for antiretroviral drugs for HIV/AIDS.[31]

In the article, Canadian and US researchers, Read Beall, Randall Kuhn and Amir Attaran construct a database of compulsory licensing activity for antiretrovirals. They then compare the prices attained through compulsory licensing against those in the WHO's Global Price Reporting Mechanism and the Global Fund's Price and Quality Reporting Tool. The authors find that "Compulsory license prices exceeded the median international procurement prices in nineteen of the thirty case studies, often with a price gap of more than 25 percent".[32]

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[31] Beall RF, Kuhn R and Amir Attaran (2015). Journal of Health Affairs, 34(3): 493-501. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25732501

[32] Beall RF, Kuhn R and Amir Attaran (2015). Journal of Health Affairs, 34(3): 493-501. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25732501

In other words, if developing countries want to obtain cheaper drugs, especially for HIV/AIDS drugs, circumventing patents by issuing a compulsory licence is not a good strategy for securing the best price. The best price is more likely to be obtained through voluntary negotiations.

Separation of powers

The Draft IP Policy strongly implies that the judicial process which occurs before the Court of the Commissioner of Patents is inadequate and should be replaced by a quicker and more affordable process. Therefore, this will presumably become an administrative rather than judicial process, under the purview of the executive government and not the courts. The fact that decisions of the Commissioner can be appealed is also problematised.

The policy, however, goes into no amount of detail as to what it intends to replace this process with, if at all. The impression is certainly created that the existing system is not to government's liking and that a different one is intended.

Without details on the replacement system, the policy has only succeeded in introducing uncertainty into South Africa's intellectual property regime. Whatever is decided, the new administrative process must allow for appeal to the ordinary courts of law and must not be of such a burdensome nature that appeals to the courts are made practically impossible.

Conclusion

Intellectual property rights standards are improving in most countries across the globe; but South Africa seems to be bucking the trend according to virtually all its proposed new laws and regulations. When it comes to international investment, we must recognise that the decision whether to invest in a foreign country is a complex one based on a variety of factors such as energy availability, labour laws, impartial courts, size of the domestic market etc. While a robust and effective IPR regime would not be sufficient in and of itself to attract foreign direct investment to our shores, a weak or poorly enforced IPR regime will deter innovative companies from investing here.

If the Draft IP 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.

Prof Karjiker points out that "For purposes of argument, let us assume that the economic literature is inconclusive about the importance of strong intellectual property law to a knowledge-driven economy, the rational course of action would not be to go for broke and dilute, or expropriate, the property rights afforded by intellectual property law. One would expect a cautious, prudent approach to such matters, and not plunging in with headlong haste, or reckless disregard for the economic consequences. There is a real danger that the proposals in relation to the substantive examination of pharmaceutical patents will cause the patenting system to grind to a halt, which could do untold damage to our reputation in relation to the protection of intellectual

property. What we could provide for is a group within DTI whose function it is to investigate pharmaceutical patents, and, if any patents are found to be invalid, that group could institute revocation proceedings".[33]

Indeed, rather than trying to make it easier to expropriate property and thwart innovation, policy makers should enact simple reforms that will improve access to medicines. One urgent reform would be to overhaul the process of registering medicines and devices. SA's drug regulator, the Medicines Control Council (MCC), or its successor, the newly formed South African Health Products Regulatory Authority (SAHPRA), which takes several years to approve a drug that often has already been approved by advanced country drug regulators. This bureaucratic inertia has resulted in a backlog of thousands of drug applications and is denying patients' ready access to medicines that could cure or manage their symptoms. For cancer and HIV patients, these delays are often fatal.

One solution to improve the registration timelines would be for SAHPRA not to attempt to undertake the entire review process itself, but rather to draw on the work of larger, better-resourced foreign drug regulators. This would prevent duplication of efforts, save public money, and speed up access to medicines.

The Draft IP Policy takes SA in the wrong direction. Robust IP protections will foster local innovation and attract committed investors who can drive SA's economic growth and human development long into the future. Without them, we will never make the transition from a resource-based economy to one based on knowledge and ideas.

The outcome of the proposals contained in the Draft IP Policy are entirely predictable – South Africa's citizens will experience a material decline in their overall health and wellbeing. South African citizens need to make a concerted effort and demand that South Africa's property rights regime is strengthened, not diminished. This will attract foreign direct investment and give confidence to South Africa's citizens that any property they acquire (both tangible and intangible) will be protected. The maintenance of IPRs protection is thus vitally important for South Africa to continue experiencing economic and health gains.

Prof Kelly Chibale states that securing and managing IP in medicines is in the best interests of the patient and to protect the poor. "It is not always about commercial returns. Government needs to see the private sector as a partner. No organisation can do this alone. The role of government is to provide an enabling environment, including incentives, and not to create disincentives which are roadblocks to unlocking potential and are preventing the creation of high-value jobs. SA cannot afford to live in a bubble because we are part of a global village. It is time to create opportunities by sharing knowhow and expertise to fast track medicine development and job creation in SA and the rest of the African continent".[34]

The latest Global IP Index published by the Global Intellectual Property Center (GIPC) demonstrates, with statistical analyses, how IPRs drive economic activity, deliver socio-economic benefits and attract FDI. The 2017 Index benchmarks the IP standards in 45 countries, representing approximately 90 percent of global GDP. The Index reveals that valuing and protecting IP is essential to building competitive, knowledge-intensive, innovative and creative 21st century economies. The GIPC's Global IP Index demonstrates that SA has seen a substantial deterioration in its national IP environment. Its score has decreased from 39% (11.74 out of 30) in the fourth edition to 36% (12.70 out of 35) in the fifth edition.

According to Meir Pugatch, a professor of intellectual property, innovation and entrepreneurship at the University of Maastricht and lead author of the GIPC International IP Index, "South Africa is changing its

[33] Prof Sadulla Karjiker (2017) IP: Politics and Beyond. Inaugural lecture, pg. 9

[34] Prof Kelly Chibale (2017). Economic and health impact of intellectual property rights on pharmaceutical research and development. Available at: https://www.youtube.com/watch?v=JJwDUceU6pc

intellectual property laws, a move that experts from research firm Pugatch Consilium argue will narrow access to medical treatments and harm the country's investment attractiveness in the pharmaceuticals sphere".[35]

South Africa's weakening position on IP rights is also to be seen in the 2017 Biopharmaceutical Competitiveness and Investment (BCI) Survey. South Africa persistently ranks amongst the worst performing nations. This lack of forward movement is giving innovators pause for concern. India and Mexico are other examples of countries wavering or backtracking on commitments to strengthen their regulatory and IP systems and, like South Africa, are experiencing a drop or a stagnation in their BCI scores. Executives cite uncertainty about the current IP policy process in South Africa and suggest that the proposed changes are eroding companies' confidence in the country as a viable investment destination. More specifically, South Africa's degrading regulatory system is scored in the "bottom category" of performance with executives citing, "Long drug approval delays of at least five years… [and] inadequate regulatory capacity, notably with regard to complex drugs".[36]

South Africa is judged by the company we keep. South Africa must not strive to emulate the policies of the worst performing countries – we have the potential to be an investment superstar. We have highly skilled scientists and engineers, and a diverse population on which to conduct clinical trials. But, instead of adopting polices that will attract investment, we are taking the path of those ranked at the bottom of the pile. Due to the increasing competition for a slice of the available pool of investment, it is no longer appropriate to simply have the minimum standards of protection. In a globally competitive world such policies do not cut it. South Africa should be aiming to be ranked amongst the top ten countries. For this to happen, we must have stability and policies that investors find attractive.

The IPRs debate and the proposals contained in the Draft IP Policy divert attention from basic issues of healthcare and vilify companies that want to earn a return on their substantial investment in this country. South Africa will not remain a poor developing country forever. If we want to build up this country's global trademarks, brands and exports, and aspire to be a global player in research, development, and manufacturing, and an exporter of high value-added, innovative products, South Africa's legislators must scrap this Draft IP Policy and get to grips with the real barriers. If they want a healthy nation to provide the manpower and energy to grow the economy, they need to eliminate the barriers that impede access to essential, already proven, off-patent medicines.

If South Africa does not respect international investors, they will simply invest elsewhere. To them, South Africa is not a special case. A cornerstone of the TRIPS agreement is the issue of national treatment, which, simply put, means that the South African government cannot discriminate against foreigners. If South Africa limits IPRs, it will be limiting the IPRs protection of its own citizens.

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[36] Pugatch Consilium (2017) Biopharmaceutical Competitiveness & Investment (BCI) Survey, 5th Edition: Ascending to the Peak of Biopharmaceutical Innovation