FREE MARKET FOUNDATION

Draft National Policy on Intellectual Property, 2013

Submission

Free Market Foundation of Southern Africa

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Introduction

The Free Market Foundation of Southern Africa (FMF) welcomes the opportunity to comment on the Department of Trade and Industry's "*Draft National Policy on Intellectual Property, 2013*" (The Draft Policy), published in the Government Gazette on 4 September 2013 in General Notice No. 918 of 2013.

The FMF is South Africa's leading property rights champion. Throughout its thirty-eight year history, it has fought more resolutely and consistently than any other role-player for the unambiguous recognition and protection of all 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.

The Draft Policy has been years in the making and there has been much speculation over the course that it would take. However, it is difficult to make a detailed submission, as the Draft Policy has been poorly drafted. The Draft Policy contains a number of statements that are subjective and not supported by any empirical research, and is littered with typographical errors and drafting inelegancies. A few glaring issues worth mentioning at the outset are:

This Draft Policy, like others emanating from the DTI during recent years, does not seem to have been drafted by someone familiar with South African law. Indeed, the architect(s) of the Draft Policy do not appear to be aware of the extent to which intellectual property (IP) is protected by other existing laws. For example, the Draft Policy makes no reference whatsoever to the Intellectual Property Rights from Publicly Funded Research and Development Act (Act 51 of 2008) which came into force in August 2010.

The Draft Policy is meant to cover all manner of IP yet there is a distinctive focus on intellectual property rights (IPRs) relating to the pharmaceutical sector. For this reason, we have focused attention on the importance of a strong intellectual property rights environment for the development of this sector and the associated benefits to South Africa's citizens. Our position is that patent legislation should be crafted to protect new inventions, advancements and improvements in a manner that is consistent across all technology-driven sectors and in accordance with the World Health Organization (WHO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Advancements in health care technology and the medical field are important contributors to gains in health and longevity globally, and thereby greatly affects productivity and economic growth. The development of innovative pharmaceutical products plays a significant role in ensuring continued gains. To encourage the continued development of pharmaceutical products, it is imperative to provide economic incentives to bring to market these advancements. The principal incentives are the price mechanism and the laws and regulations that foster innovation.[1]

Intellectual property laws play an integral role in the range of laws required to promote and foster innovation within any economy. These laws confer certain exclusive rights on innovative ideas so that the developers and entrepreneurs involved in their testing and refinement are allowed a limited

[1] U.S. Department of Commerce, International Trade Administration (2004) Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development and Innovation

period in which to capitalise on those new products to recoup some of the vast amount of funding spent during the development and trial period. Intellectual property rights protection for pharmaceutical innovations is, generally, granted for a maximum period of 20 years. Once this 'window of opportunity' to capitalise on an idea closes, the product falls into the public domain and generic companies are allowed to copy and benefit financially from the original idea.

Private organisations bring to market the vast majority of new developments. Without IPRs protection, they would be less able to assume the costs and risks associated with bringing new products and ideas to market. The 'window of opportunity' not only rewards innovators for their ideas, but also encourages future developments, and maximises scientific progress and access to new products. In the field of pharmaceutical products, this policy ensures that innovative pharmaceutical companies can recoup the enormous amount of time and expense that goes into developing new drugs, whilst promoting generic competition after the expiration of the patent term.

It is important to note that innovative medicines are the necessary pipeline for generics. The production of generics depends on initial registration and market development of the original product by innovators. In other words, IP protection is a necessary prerequisite to attract innovative companies to invest locally. Poor enforcement, or lack of IP protection, discourages multinational companies from registering and manufacturing new products locally and they withhold their investment. A limited source of innovator medicines would eventually lead to a stagnant generic drug market.

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]

South Africa has a proud record of upholding IPRs unlike elsewhere on the African continent. It has been one of the factors that has attracted a high level of foreign pharmaceutical investment to this country and contributed to the development of the local industry. It has allowed South African citizens to have greater access to some of the world's most advanced medications and has resulted in them enjoying better health.

[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

Detailed Submission

The author of the Draft Policy confuses various international agreements. For example, in Chapter 12, the author states, "Article 6 of the TRIPS Agreement provides that a member state of the WTO may notify (through WIPO) other states that its emblems should not be used by other states and their agencies or nationals without consent of the member state concerned". Article 6 of the TRIPS agreement refers to "Exhaustion". It has nothing to do with the use of national emblems.

The author of the Draft Policy appears to think that South Africa is a Least Developed Country (LDC) and that Section 66 of the TRIPS agreement could apply to South Africa. South Africa is not a LDC. This section has no relevance whatsoever to South Africa and should be removed from the Draft Policy.

Even after a careful reading of the "Problem Statement", one is left wondering what the problem is. As stated previously, many of the supposed problems are already covered by existing legislation. For example, patents are seen as a major barrier to access to medicines. The author seems unaware of the fact that the Patents Act makes provision for the granting of compulsory licences in certain circumstances. The FMF's view is an inordinate amount of emphasis has been placed on pharmaceutical products and very little, if anything, has been said about other forms of IP.

For these and other reasons detailed in the following subsections, we recommend a complete redraft of the Draft Policy. In what follows, we provide a thorough commentary on issues that warrant more detailed attention. The FMF pledges our assistance with any attempt at addressing these and other concerns.

Search and examination

The Draft Policy proposes the introduction of a "substantive search and examination" based patent registration system. For example, Chapter 1 states, "The form of IP associated with technology is the patent. Due to this, there is an outcry by users of the patent system that South Africa needs strong patents that can survive the test of competitiveness throughout the world. This can be achieved if a substantive Search and Examination of Patents system is followed".

The FMF welcomes the idea of a more robust system. However, South Africa suffers from a chronic shortage of skilled personnel with the necessary capabilities for handling a more intensive and extensive system. South Africa is also a developing country and lacks the necessary financial resources to administer a "substantive search and examination system".

Without the necessary skills (both technical and administrative) and financial resources to administer this system, significant delays in the process will be likely. This will have the unintended consequence of deterring investment. Given the fact that virtually all developed economies have examination systems and most patents registered in South Africa come from developed countries, it would be unwise to duplicate these efforts.

Most large companies are well versed with search and examination type systems and have the resources to navigate through the process. In contrast, South African companies are not familiar with the process and it 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 not have the time and resources to find a way through the process.

Connectivity of databases

The Draft Bill proposes the integration of the South African Medicines Control Council (MCC) and the Companies and Intellectual Property Commission (CIPC) databases. The Draft Policy states, "Government departments should integrate their databases for the purposes of sharing information so as not to grant patents on medicines that may be expiring as this may undermine access to public health".

This is a disastrous proposal. For all intents and purposes the MCC is a dysfunctional organisation. For this very reason, the South African government is proposing the introduction of a new regulatory authority, the South African Health Products Regulatory Authority (SAHPRA). The stated aim of the SAHPRA is to replace the MCC and to take responsibility for overseeing the registration of both medicines and medical devices (which have not been subject to the registration process up to this point). It is unlikely, however, that the new SAHPRA will be able to resolve all the problems and reduce the backlog in a short space of time because of the chronic lack of expertise in South Africa.

Delays in the registration of innovative medicines will impact South Africa's future access to generic products. Before a generic can be sold, marketing authorisation has to be obtained from the MCC, an authorisation (registration) that is based on an already registered product in South Africa, i.e. an innovative product.

According to the Department of Health (DoH) Annual Report for 2011/2012, one of the key objectives of the sub-programme *Pharmaceutical Trade and Product Regulation* is to "Improve the registration of medicines and reduce the time to market by reducing the backlog on medicine registrations...".[3] The baseline values reported in the 2010/2011 report show that the average time for the registration of a new chemical entity (NCE) was 32 months and 30 months for generics.[4] The DoH notes that these timelines "include up to 9-12 months of the applicant's time to respond to a committee resolution".[5] Hence the actual average evaluation time by the MCC is 23 months for NCEs and 21 months for generics.

The DoH set itself the target of registration timelines of "30 months for NCEs and 18 months for generics".[6] However, according to the 2011/2012 annual report, "386 generics were registered in an average of 34 months" whilst "34 human NCEs were registered in 37 months".[7] The annual report also notes "47 outliers (part of the backlog) were registered, ranging from 50 months to 14 years".[8]

Thus, in an age of tremendous scientific and medical progress offering new hope to South African patients, the MCC actually lost ground from the base year (2 months for NCEs and 4 months for generics) and reported a variance of 16 months for generic registrations and seven months for NCEs based on its 2011/2012 target.

In both cases, many of the drugs concerned had already been registered for use in the US, European Union, Japan and other developed nations. To relieve the burden on the MCC, the FMF has proposed that the MCC should identify a handful of reference regulatory agencies that it deems competent.

[3] Department of Health Annual Report 2011/2012
[4] ibid
[5] ibid
[6] ibid
[7] ibid
[8] ibid

For example, it may decide that the United States Food and Drug Administration (FDA), Health Canada, the United Kingdom's Medicines and Health Products Regulatory Agency (MHRA), Australian Therapeutic Goods Administration (TGA) and the European Medicines Agency (EMA) are sufficiently stringent regulators. Drugs which have already been approved by two or more of these advanced country drug regulatory authorities, should simply gain automatic approval in South Africa. This will ensure that medicines, both generics and originator, which have already been approved by advanced country regulators will reach South African patients in a timely manner.

Similarly, South Africa should conserve scarce resources and continue using the depository system. Patents that have already undergone a substantive search and examination in developed countries should be entitled to a presumption of validity.

Patents can still be challenged after they have been granted. The FMF, therefore, believes that the DTI should reconsider its proposal to introduce a pre-grant opposition system. A pre-grant opposition system has the potential to be used inappropriately and frivolously. It will cause unnecessary delays which are likely to deter investment and prevent life saving pharmaceutical products from entering our economy.

Streamlining operations

One of the recommendations in Chapter 2 states, "South Africa should make provisions in its laws that will facilitate the entry of generic competitors as soon as the patent has expired on a particular medicine. The Bolar provision is already in the Patents Amendment Act 2002. Quick generic approval by the MCC (predecessor of the Medicine Regulatory Authority, which used to be imbued with backlogs of some sort)".

The second sentence in this "recommendation" appears to be the answer to the first sentence. Although the third sentence is factually incorrect, it is disappointing that the DTI singles out generics for "quick approval". Surely the aim would be to obtain "quick approval" for all medicines, both generic and originator?

TRIPS flexibilities

Recommendation 1 of Chapter 2 states, "Compulsory licensing should be introduced in South Africa..."

The author of the Draft Policy does not seem to be aware of the fact that South African laws already make provision for the granting of compulsory licences in emergency situations. Section 56 of the Patents Act makes provision for compulsory licensing.

Recommendation 3 of Chapter 2 states, "South Africa should facilitate in its legislation the ability to import patented products if it can get them cheaper in other jurisdictions (parallel importation)."

Once again, South African laws already provide for parallel importation. Through its commitment to increase access to medicines, the South African government made provision for compulsory licensing and parallel importation in the Medicines and Related Substances Control Amendment Act of 1997.

It was these provisions that civil society groups targeted in 2000 when they brought the matter before the courts and argued that that IPRs regime was restricting access to anti-retroviral (ARV) medicines used to treat HIV/AIDS in South Africa. They claimed that patent protections on ARVs were preventing access to these treatments and that the government should use the TRIPS flexibilities to lower prices. The result was a compromise and innovator companies *voluntarily* agreed to license out production and/or distribution of their ARV drugs. This compromise, however, was an uneasy one, because, without it, government would have simply forced innovator companies to provide their ARVs to domestic manufacturers via the flexibilities provided through the TRIPS agreement.

The FMF is of the view that this erosion of IPRs protection is partly responsible for the decline in the number of innovative companies marketing ARVs in South Africa. This uncertainty has probably contributed to the decrease in investment and attractiveness of South Africa as a viable destination. For these reasons, we cannot support an expansion of the use of compulsory licensing or parallel importation through the Draft Policy.

Price controls

Recommendation 2 in Chapter 2 states, "For the IP and health policies to be in tandem, the DTI and the Department of Health should reconcile policy stances. In this regard, there is a need to address the pricing of drugs as it may frustrate issues of access to public health". This statement seems to imply that the government intends to introduce further price controls in the pharmaceutical sector.

Price controls seem to be a favourite policy intervention by legislators because they assume that, by a simple stroke of the statutory pen, access to the commodity in question will increase. They are mistaken because the market is far more complex and the price mechanism, which plays an intricate role in sending signals to producers and consumers, cannot be overruled.

Price controls bring about unintended consequences and, undoubtedly, will produce the opposite effect and reduce access to medicines. Large established businesses often tolerate or even welcome regulated price controls because one major consequence is that they act as a barrier to entry and keep competition out of the industry. Regulated prices that are kept low, allow very little profit to be made and thus deter entrepreneurs from entering the market.

An unfavourable pricing regime definitely impacts on any decision to launch innovative products. A Deloitte study shows that the contribution of the multinational pharmaceutical industry to the South African economy is most vulnerable to price decreases.[9] Drug price regulations, in addition to the delays in registering drugs and the reduced overall availability of innovative new medicines, will force more and more pharmacies and wholesalers into bankruptcy or closure and ensure that the distribution of drugs to rural and remote areas will be financially unviable.

[9] Deloitte (2010) Insights into the high-level financial contribution of the Pharmaceutical Industry in South Africa

State generated IP

The government recognises the importance of protecting IP. Chapter 12 of the Draft Bill states, "The state generates a lot of IP and is entitled to protect its own IP".

If another country should begin producing Rooivalk helicopters or some other government generated IP, it is certain that the South African government would vigorously defend its IP. Similarly, if it started producing its own medicines and another country produced the same ones without permission from the South African government, again government will institute some form of punitive measures.

The Draft Policy contains many recommendations that will weaken the IPRs of foreigners and certain companies based in South Africa, most notably originator pharmaceutical companies, on the basis of "access to public health" and the "Development Agenda". The government must recognise the fact that if it weakens IPRs for some, it weakens them for all.

Concluding Remarks

The maintenance of IPRs protection is vitally important for South Africa to continue experiencing economic and health gains. The South African government may never have enforced the flexibilities contained within the TRIPS agreement, but the compromise reached by innovator or research and development (R&D) based firms after the court case brought by civil society surrounding access to HIV/AIDS treatments has severely undermined the IPRs environment. It has caused many firms to reconsider their investment in South Africa and deterred other future investment.

Although a sound IPRs environment is a necessary condition to achieve better health and economic outcomes, it is not sufficient. Complimentary laws and institutions are a vital component. Governments may have well-meaning intentions to increase access through the introduction of new laws and regulations but, often, the consequences of such laws and regulations have the opposite effect and in the case of pharmaceutical products, actually reduce access to medicines.

Throughout the Draft Policy, IPRs is viewed as a major barrier to access to pharmaceutical products. This does not explain why products that are off-patent are not reaching the patients who need them. Lee Gillespie-White and Amir Attaran have demonstrated that over 95 per cent of the drugs contained in the WHOs Essential Medicines List (EML) are off-patent.[10,11]

Civil society groups, supposedly acting on behalf of those suffering from ill-health in South Africa, place an inordinate emphasis on patents as a major barrier to access to pharmaceutical products. The real problem for the vast majority of South Africans, in fact, is not 'access to drugs', but to 'quality healthcare'.

Diminishing patent rights will definitely harm South Africa's aspirations in IP sensitive sectors, but not affect South Africa's morbidity and mortality burden as much as the civil society groups

[10] Attaran, A. and Gillespie-White, L. (2001) "Do patents for antiretroviral drugs constrain access to Aids treatment in Africa?" Journal of American Medical Association, vol. 286 no. 15 pg. 1886-1892.
[11] Attaran, A. (2004) "How do patents and economic policies affect access to essential medicines in developing countries?" Health Affairs, vol. 23, no. 3.

envisage. Hundreds of thousands of South Africans suffer on a daily basis because, besides receiving inadequate care, essential, off patent, proven drugs are not being made available to them.

Critics of the current IP laws in South Africa persistently refer to the IP regimes in countries like Brazil and India. What is it that makes them think these countries are worthy of admiration? We believe that Brazil and India rather should take a leaf out of South Africa's book. And that South Africa should be looking to adopt policies that foster investment and economic development.

The FMF is a partner organisation of the Property Rights Alliance (PRA). Each year they publish the *International Property Rights Index* (IPRI) which is an annual comparative study of countries around the world that aims to quantify the strength of their property rights – both physical and intellectual – and to rank them accordingly.[12] The recently published 2013 IPRI measures the intellectual and physical property rights of 131 nations. It scores and ranks each country based on 10 factors reflecting the state of its Legal and Political Environment (LP), Physical Property Rights (PPR) and Intellectual Property Rights (IPRs). On average, countries in the top quintile (top 20%) of the IPRI show a per capita income approximately seven times that of the bottom quintile countries.

The IPRI emphasises the economic differences between countries with strong property rights and those that have little or none. South Africa ranks 26th overall, a position that it should be proud of and one that we should vigorously defend. In contrast, Brazil and India rank 56th and 58th respectively and are not countries that South Africa should be striving to emulate.

Countries that record high incomes per capita and long life expectancies all embrace strong IPRs. The study shows that countries with low scores prosper if their scores are increasing. Conversely, countries with high scores stagnate if their scores decline. This alerts us to the fact that high-scoring countries, such as South Africa, are punished severely if they compromise property rights, whereas low-scoring countries are rewarded generously if they enhance property rights.

In the *Economic Freedom of the World 2013 Annual Report*, Brazil and India are ranked 102nd and 111th respectively in contrast to South Africa which ranks 88th overall.[13] The Economic Freedom of the World (EFW) report demonstrates that economic freedom and growth are inextricably linked and one of the cornerstones of economic freedom is the respect of property rights. More specifically, the report objectively determines that the freest economies in the world have average per capita incomes of US$36,466 (R364,660) whereas the least free economies have average per capita incomes of US$4,382 (R43,820). Moreover, the EFW report shows life expectancy is approximately 20 years longer in countries with the most economic freedom (79.2 years) compared to those with the least (60.2 years).

The IPRs debate and the proposals contained in the Draft 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 Policy and get to grips with the real barriers. And, 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.

[12] Property Rights Alliance (2013) International Property Rights Index, 2013. Available at: http://www.internationalpropertyrightsindex.org/

[13] Fraser Institute (2013) Economic Freedom of the World, 2013 Annual Report. Available at: http://www.freetheworld.com/release.html

Countries characterised as “winners”, have strong IPRs. To lower South Africa’s IPRs standards would be tantamount to relegating its citizens to the levels that characterise “loser” countries.

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.