TREATMENT ACTION CAMPAIGN

FIX THE PATENT LAWS!

RESEARCH PAPER

The Economic & Social Case for Patent Law Reform in South Africa

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Terminology

Intellectual Property (IP): Rights protecting creations of the mind (such as inventions, designs, literary works etc) including patents, trademarks, geographical indicators and copyright.

Patent: An exclusive right (or reward) granted by the state to an inventor for his/her intellectual property. During the patent period of 20 years, no one else can make, use, import, market or sell the patented product other than the right-holder. The purpose of this reward is to stimulate innovation into products that benefit society.

World Trade Organization (WTO): The WTO develops and oversees rules of trade between its members (159 members) – South Africa has been a member of the WTO since 1995.

TRIPS: The Agreement on Trade Related Aspects of Intellectual Property, commonly called the TRIPS agreement, binds WTO member countries to uphold a certain level of intellectual property protection nationally. TRIPS came into effect in 1995.

Doha Declaration: Given the effect of the TRIPS agreement on public health, certain legal flexibilities or safeguards within TRIPS were affirmed in 2001 under the Doha Declaration. The safeguards seek to protect countries' abilities to achieve the right to health.

Patentability Standards: Criteria defined by national legislation that sets out what level of innovation is deserving of patent protection. Innovation must be novel, involve an inventive step and be capable of industrial applicability.

Research and Development Multinational Corporations (R&D MNCs): Multinational companies that invest in the development of new medicines and other medical tools and seek out patents globally to protect their economic interests in profitably marketing these products.

Introduction

The Treatment Action Campaign (TAC) and Médecins Sans Frontières (MSF) launched the 'Fix the patent laws' campaign on November 11 2011 – the ten year anniversary of the WTO's Doha Declaration on TRIPS and public health. The campaign aims to draw attention to problems with South Africa's national patent laws that negatively impact upon access to affordable medicines.

This paper seeks to respond with evidence and reasoned analysis to a number of claims that have been made by the international pharmaceutical industry in response to the Fix the Patent Laws campaign. We provide evidence that adopting TRIPS safeguards will not only benefit public health efforts, but will also benefit local industry and economic development. Additionally, the paper highlights the flaws in claims that protecting health in South Africa will inhibit the development of future medicines.

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Impact on Foreign Direct Investment:

It is often assumed that stricter intellectual property leads to an increase in foreign direct investment. Will the introduction of safeguards to protect public health reduce future economic investment?

In 1994, WTO members signed the TRIPS agreement which came into effect on 1 January 1995. South Africa became a member of the WTO on the same day. TRIPS set out the standards of intellectual property protection that all countries would be required to uphold. South Africa amended its national laws to comply with these requirements in 1997, extending periods of monopoly protection from 16 years to 20 years, despite the fact that South Africa was not obliged to comply with TRIPS until 2000 in accordance with the TRIPS transitional period.

When negotiating the agreement, developed countries promised developing countries that the implementation and expansion of intellectual property protection would result in greater foreign direct investment which would stimulate economic growth. Yet since expanding patent protection, the opposite has been observed in South Africa.

Following the adoption of TRIPS, South Africa witnessed a massive decline in pharmaceutical production and investment by R&D MNCs. Between 1994 and 2007, 35 pharmaceutical manufacturing plants in South Africa, belonging mainly to R&D MNCs, were shut down (Maloney & Segal, 2007). Rather than expanding investment in countries with strengthened intellectual property protection, R&D MNCs consolidated their operations in regions with skilled labour, low costs of labour and production and other economic incentives (Naude & Luiz, 2013). In the past decade, investment by companies producing generic medicines in South Africa's pharmaceutical market has massively outpaced that of R&D MNCs (DTI, 2011), yet our laws have limited the growth of this industry.

Furthermore, empirical evidence to support the claim that strengthening intellectual property will result in increased investment is limited. Academic studies have found conflicting results: 'Proof of a correlation between strong intellectual property rights and foreign direct investment…remains elusive' (Musungu, 2005). For example, India's pharmaceutical industry realised foreign direct investment of US$1 billion from April-June 2013, despite India's proactive adoption of legal TRIPS flexibilities to limit intellectual property protection specifically in order to protect health and local industry (The Economic Times, 2013). Conversely, South Africa has attracted far less foreign direct investment than other countries with weaker intellectual property protection (Kaplan, 2009).

A recently published study that investigated the relationship between intellectual property protection and foreign direct investment in 103 countries between 1970 and 2009 found that strict intellectual property protection can actually negatively impact on growth associated with foreign investment. The study found that countries that are able to attract foreign investment, while simultaneously retaining 'lax' levels of intellectual property protection were able to achieve a higher growth rate (Kascheeva, 2013).

Impact on Local Industry and the Economy:

What is the impact of strengthened intellectual property on the growth of South Africa's pharmaceutical industry and economy?

Empirical analysis have shown that South Africa grants an excessive number of patents in comparison to both developed and developing countries. In 2008 alone South Africa granted 2,442 pharmaceutical patents, while Brazil only granted 278 pharmaceutical patents between 2003 and 2008 (Correa, 2011). Unpublished research by academics from Columbia University, Yale University and the Medicines Patent Pool, presented at a 2012 TAC/MSF conference, showed that South Africa is granting 40% more pharmaceutical patents than the US and EU on identical applications (Sampat et al., 2012).

South Africa does not substantively examine patent applications to ensure they meet the country's patentability standards. Additionally, applying for a patent in South Africa is, on average, around 20 to 30 times cheaper than most patent offices, which opens the country up to frivolous and abusive patent applications (Pouris & Pouris, 2011). A 2011 study by the University of Pretoria's Institute for Technological Innovation found that around 80% of patents upheld in South Africa fail to meet the country's patentability standards (Pouris & Pouris, 2011).

Granting an excessive number of patents (including patents on the same compound) is not only problematic for health, but also for the development of South Africa's local industry. Pharmaceutical companies that are locally manufacturing medicines produce almost exclusively generic, not patented, medicines. By granting an excessive number of patents, South Africa is actually protecting the interests of foreign MNCs at the expense of local producers who are unable to enter the market for extended periods of time - in fact, of the 2,442 pharmaceutical patents granted in South Africa in 2008, only 16 were held by local companies (Vawda, 2011).

For example, the original patent on Bayer's contraceptive pill Yasmin expired in 2010. Secondary patents on Yasmin were rejected in Europe and the United States. However, a secondary patent on Yasmin was granted in South Africa which means that domestic pharmaceutical company Pharma Dynamics is currently prevented from bringing their generic version of Yasmin to market in South Africa. This leads both to higher prices for local consumers and to greater outflows of money – which contributes to South Africa's pharmaceutical trade deficit (Child, 2013).

While foreign MNCs easily secure patents in South Africa, local inventors find it difficult to protect their patents abroad – largely due to the high cost of filing patents in other countries. Between 1996 and 2006, 280 patents were granted in South Africa to local academics and universities, but only 20% of these patents were also protected abroad (Pouris & Pouris, 2011).

In contrast to South Africa, India utilised the TRIPS extension period allowing middle-income countries to delay TRIPS compliance (extension periods for TRIPS compliance were provided to middle and lower income countries on the basis of their level of development). India's law did not provide for patents on pharmaceutical products from 1970 until 2005, during which time the country's pharmaceutical industry flourished. India was a net importer of medicines until 1988, but by the mid-90s India reversed this deficit, generating a large trade surplus (Pharma Focus Asia) and becoming what is now referred to as the 'pharmacy of the developing world'. In 2005, India amended its national legislation to comply with TRIPS yet, unlike South Africa, India adopted legal safeguards to protect public health as well as local industry. Today, India retains its dominance as a global supplier of affordable generic medicines – supplying 80% of the generic

medicines across the world (Waning et al, 2010). In 2010, India's generic industry was worth US$12.24 billion (R137.83 billion) (Frost & Sullivan, 2012). In comparison, in 2011 the entire South African pharmaceutical market was worth only $3.8 billion (R42.77 billion) (GBI Research, 2012).

In fact there is no conclusive evidence that intellectual property stimulates the economy, particularly in the developing country context (Maskus, 2000; Qian, 2007). India's experience of economic growth during a period when it did not uphold intellectual property protection is not unique. Many developed countries provided weak intellectual property protection during their transition into highly industrialised, developed economies. For instance, Japan, Taiwan and South Korea provided relatively low levels of intellectual property protection during early periods of development and industrialisation (Odagiri et al., 2011; Kumar, 2011). "Japan, Korea and Taiwan have absorbed substantial amounts of technological learning under weak IPR protection regimes during the early phases [of development]" (Kumar, 2011).

Many of today's developed countries were able to borrow and copy technology from wealthier countries to develop their own industries. Developed countries have therefore been accused of "kicking away the ladder" that would allow developing countries to catch-up by pressuring low and middle income countries to adopt strict IP protection (Ha-Joon Chang, 2002). A number of academics have argued that, rather than adopting the same level of intellectual property protection upheld in developed countries, developing countries should adopt standards that are more in line with their development goals.

Moreover, developed countries have themselves utilised various TRIPS flexibilities whilst simultaneously arguing against the use of these measures in the developing world, and even pushing for more harmful, TRIPS plus terms in trade and investment agreements. The United States is perhaps the world's most frequent user of compulsory licensing, including the government use of defence technologies, and judicially issued licenses to remedy anti-competitive practices in information technology and biotechnology, among other instances. Recently, six compulsory licenses on medical technologies were granted by courts in the United States, this whilst simultaneously placing India on the US Special 301 Watch List for their own use of pro-access safeguards. It is also important to note that the US PEPFAR programme almost exclusively sources generic medicines and has become the world's largest consumer of generic products manufactured under compulsory licenses (Love, 2012a).

Impact on the Trade Deficit

Strict IP protection not only impedes the growth of local industry, but also contributes to a negative balance of trade. According to IMS figures, in 2012 South Africa spent R5 billion procuring pharmaceutical products (Aspen Pharmacare, 2012). The Department of Trade and Industry has noted the contribution of imported medicines to the trade deficit as a key area of concern - pharmaceuticals are the 5th largest contributor to South Africa's trade deficit (DTI, 2011). Yet, there has been little analysis or mention of the extent to which excessive patenting drives the country's deficit.

By volume, South Africa imports the majority of its medicines from India, and the majority of its active pharmaceutical ingredients from China (DTI, 2011). However, the top 5 countries from which South Africa imports medicines in terms of expenditure are, in order: Germany, the USA, France, India and the UK. Tellingly, this list does not include China, and India only falls in the 4th position (Deloitte, 2010). These figures strongly suggest that the importation of branded

medicines is a significant, if not the main, driver of the deficit. It is reasonable to conclude that granting fewer patents of poor quality will contribute to a reduction in the pharmaceutical trade deficit – both by reducing prices and by enabling an increase in local production of generic medicines.

The Affordability of Medical Innovation:

There is a widespread assumption that strict intellectual property is essential to recoup the costs of drug development and ensure all future innovation. What is the real impact of incorporating public health safeguards into intellectual property laws on the future development of medicines?

R&D MNCs commonly caution that any reduction in intellectual property will be calamitous for the development of future medicines by removing their ability to invest in research and development (R&D). However, in reality, if South Africa adopts safeguards to protect health into its laws there is likely to be minimal - if any - impact on the development of future drugs. The South African market accounts for a very small portion of global pharmaceutical sales. The whole of Sub-Saharan Africa only accounts for 1.2% of global pharmaceutical sales. By comparison, the United States accounts for 45.5% of global sales (Baker, 2010). Decisions on the global R&D pipeline and clinical development of promising new drugs are not made on the assessment of minor sales reductions in small markets like South Africa's.

Furthermore, in comparison to global yearly medicine (and other medical tool) sales of US $856 billion in 2010 – the pharmaceutical industry only spent 7.9% of this on R&D efforts (Love, 2011). Expenditure by pharmaceutical companies on R&D pales in comparison to expenditure on marketing and profits. Pharmaceutical companies spend almost twice as much on marketing as they do on R&D (Gagnon, 2008) while simultaneously recouping massive profits. The pharmaceutical industry commonly takes home more in profit each year than it spends on R&D costs. From 1995 – 2002, the pharmaceutical industry was ranked the most profitable industry in the United States. In 2008 and 2009, the industry continued to feature amongst the country's most profitable business sectors, claiming the third spot in both years (Fortune 500 Rankings). On top of this, even GlaxoSmithKline's CEO Andrew Witty has publicly stated that the huge price tag of US$1 billion associated with pharmaceutical R&D is "one of the great myths of the industry" (Reuters). Based on the over generous claims made on R&D costs (as detailed below) we can assume that the 7.9% figure is in itself higher than the actual cost.

Moreover, R&D expenditure is not solely the realm of pharmaceutical companies—the general public contributes an estimated 30% of total R&D spending through public funds financed by tax contributions, a further 10% is funded through other sources (including philanthropic organisations), which principally finance the earliest, most risky stages of development (Røttingen J-A, 2013). In South Africa, figures from 2009/2010 show that the government was the largest funder of R&D, contributing 44.4% (DST, 2013a).

To demonstrate the cost implications, Knowledge Ecology International (KEI) provided an independent assessment of Novartis' development costs for the cancer drug imatinib, considering both risk of failures and cost of capital. By the most generous estimate, Novartis' outlay on R&D for imatinib was US$96 million, with the company contributing only 10% of early research costs. Yet in 2012, sales of imatinib generated US$4.7 billion globally – ensuring Novartis realised a return on their investment once every 13 days (Love, 2013a).

In addition KEI assessed development costs for the cancer drug sorafenib. Bayer publicly estimated the R&D costs for sorafenib at $2.5 billion. However, KEI's independent assessment shows that the entire outlay amounted to $295.7 million, with the company contributing $26.1 million between 1994 to 1999 following which R&D costs were split equally between Bayer and partner company Onyx Pharmaceuticals at $134.8million each. Furthermore some of the development costs for sorafenib benefited from orphan drug designation (US tax credit). $295.7million is just 11.8 percent of the $2.5 billion estimate and ignoring the tax credits, represents just over a quarter of the current global sales for sorafenib to date (a product that will maintain its monopoly in most markets through 2020) (Love, 2013b).

In response to India's recent issuance of a compulsory licence on sorafenib, which allows generic manucturing of the medicine in the country, Marijn Dekkers, CEO of Bayer stated that the cancer drug was not developed for poor patients in India rather "for western patients who can afford it" (Gokhale, 2014). The medicine is marketed by Bayer at $65,000 per patient per year in India – a price Bayer state is "reasonably affordable" – amounting to 50 times average incomes in India in 2010 (Love, 2012b). The medicine which remains under patent in South Africa, is not available to patients in the public sector due to its high price.

Neglected Areas of Medical Innovation

Currently, the incentive for R&D MNCs to develop new medicines and medical tools lies in the reward of high profits enabled by the patent system. This means that the medical development pipeline is driven overwhelmingly by the market as opposed to health needs. Despite the protection of patents in developing countries at great expense to public health, R&D MNCs are not reinvesting their profits in diseases affecting the developing world. In 2010, global R&D for neglected disease areas (such as tuberculosis, the leading cause of death in South Africa) amounted to just $3.2 billion (G-Finder, 2011) of global R&D that amounted to $67.4 billion (PhRMA, 2011), just 4.75% in total. Further still, it is estimated that only $1 out of every $100,000 spent worldwide on biomedical R&D and product development is directed at neglected tropical diseases (Oxfam, 2008).

Market driven R&D has failed to meet a vast unmet need for disease areas that affect patients who are too poor or too few to guarantee large scale profits. For example, despite a massive and escalating need for new drugs to treat multi-drug resistant tuberculosis (MDR-TB) – a growing threat in South Africa - few new drugs have entered the market in the past 60 years, and those that have are unaffordable. For instance, linezolid, a high strength antibiotic by pfizer, with a growing body of evidence showing its efficacy in treating MDR-TB is currently marketed at R676 in the private sector in South Africa, pricing it out of reach of those in need. MSF doctors could only afford to treat 22 out of 300 eligible patients in Khayelitsha due to the high cost of providing linezolid, which must be taken for up to two years costing approxiamately $49,000.

The expansion of pharmaceutical protection under TRIPS has not led to an increase in the rate of pharmaceutical innovation (t'Hoen et al, 2011). Rather it has led to greater investment by pharmaceutical companies into evergreening - developing new formulations, new uses and new forms of existing medicines. A French study found that 68% of new products 'approved in France between 1981 and 2004 offered "nothing new" over previously available medicines' (t'Hoen et al, 2011). A US analysis showed that more than three fourths of medicines approved between 1989 and 2000 'have no therapeutic benefits over existing medicines' (MSF, 2012).

The application of low standards of patentability results in many low quality patents (FTC, 2003). R&D MNCs claim that if countries set stricter patent standards it will undermine future innovation. Rather, it will simply assist in protecting countries from abuse of low quality patents that provide no new innovation or therapeutic benefit.

Lastly, strict patent regimes can also block follow-on innovation by researchers and generic manufacturers from taking place prior to patent expiry, despite the fact that safeguards within the TRIPS agreement allow members to establish limited exceptions to patents for research purposes. This can block important follow-on drug development from occurring. For example in South Africa, as it stands, progress on developing a micro-granule paediatric formulation for treating HIV by the Drugs for Neglected Diseases initiative (DNDi) has stalled as the granules contain a medicine under patent to Abbott in South Africa. Therefore unless they ascertain the express permission of the patent holder to continue, they are unable to carry out clinical trials.

On the other hand we have seen certain follow on innovation that benefits patients in the developing world (in countries without patent protection) ahead of those in the developed world in countries with stricter IP regimes. For example generic Atripla (a triple fixed dose of tenofovir/emtricitabine/efavirenz) is currently available in much of the developing world, whilst secondary patents on tenofovir in the US mean that patients there will be unable to benefit from the combination pill until up to 2018.

Low Quality Patents Create Access Barriers:

How does the issue of secondary patents in South Africa (used to extend pharmaceutical monopolies on medicines) differ from a patent term extension to create a monopoly period?

Secondary patenting practices must be differentiated from patent term extension measures, which have recently been confused in public statements emanating from the pharmaceutical industry. A patent term extension refers to an instance when the life of the patent is extended beyond the 20 years established in the TRIPS Agreement. Patent term extensions have been pushed for in various free trade agreements by the developed world in order to counter the regulatory delays to patent registration. Our position remains that this is a TRIPS plus provision that goes beyond what is required in the TRIPS Agreement and should thus be rejected. Regulatory and patent issues should not be linked. South Africa does not currently have patent term extension measures in place and this is not how monopolies on medicines are extended here.

The pharmaceutical industry instead extends their monopolies through the use of secondary patents. Companies will file patents for new uses of medicines, or make obvious minor improvements or modifications to a known drug, in order to gain a secondary patent on the existing compound. These evergreening strategies have become increasingly prolific in recent years with negative implications on access to affordable medicines. A 2008 inquiry by the European Commission found that patents obtained are often strategically used to block competition, with originator companies designing strategies aimed at ensuring continued revenue streams (EC, 2009). Secondary patenting and subsequently engaging in patent litigation disputes, concluding settlement agreements with generic companies, and intervening in national procedures for generic medicine approval all have a direct negative impact on access to generic medicines (Correa, 2011).

A Yale University study demonstrated that secondary formulation patents added an average of 6.5 years of patent life - method of use patents add 7.4 years, and patents on new forms (polymorphs, isomers, prodrug, ester, and/or salt) add 6.3 years. The study also found evidence that secondary patents are more likely to be filed after the drug is approved and are more common for higher sales drugs (Kapczynski et al. 2012) which implies that the pharmaceutical industry wants to maintain monopoly on the most profitable medicines.

Even where generics are able to enter the market at patent expiry, a study that made comparisons between the prescriptions of patented (brand) drug, the follow-on drug, and generic versions of the drug and subsequent cost effectiveness showed these evergreening strategies substantially contributed to an increase in overall healthcare costs in a high resources setting (Vernaz et al. 2013).

Furthermore there have been examples of R&D MNCs diverting procurement to secondary patented compounds in other ways. For example in the US at the end of 2012 Reckitt Benckiser announced the withdrawal of their branded buprenorphine/naloxone combination tablets over safety concerns. Reckitt substituted their original tablets (due to come off patent in 2013) with a new form of the medicine (patented until 2022). Concurrently Reckitt filed a Citizen's Petition at the US FDA to stop approval of generic companies to produce the tablet form, yet would not remove their own tablet form from the market for a 6-month period following the announcement (Forbes, 2013).

The Wider Health System:

What will be the impact to the National Strategic Plan (NSP) and wider health system if the proposed reforms to South Africa's Patent Act are not established?

Achieving the National Strategic Plan (NSP) objectives (80% of eligible patients on ART and 50% reduction in TB deaths) as well as improving the wider health system depends on the effective use of available resources for health.

HIV-related costs are likely to increase over time. Demand for ARVs will rise as additional eligible patients are initiated on to life-long treatment in line with National Strategic Plan (NSP) targets, at earlier CD4 counts in accordance with changing treatment recommendations (WHO, 2013a). As resistance to treatment develops, people living with HIV will be shifted from first-line regimens (R1072 ppy) to second or even third-line regimens. Recent research from the National Institutes of Health shows that 16.9% of patients on ART for 5 years (in South Africa) needed to switch to a second-line drug combination because of virological failure (Fox et al, 2012). The second-line options are currently available at R2,859 ppy. The current third-line options remain under patent protection and cost R18,000 ppy (Kardas-Nelson et al, 2013). Unless the imbalance in the patent system is redressed, HIV-related costs are likely to rise sharply in the near future, restricting the success of the National Health Insurance scheme and the ability of the Department of Health to improve problems within the wider health infrastructure.

Even developed countries like the UK have rejected certain medicines based on their lack of affordability for the National Health Service. Since 2011, the National Institute for Health and Care Excellence (NICE), the UK cost watchdog, rejected the inclusion of at least seven cancer drugs for use within the National Health Service as they were priced too high to be cost effective.

The WHO Essential Medicines List:

Why do we need intellectual property reforms when the majority of medicines on the WHO Essential Medicines List already are off patent?

Industry rhetoric against pro-access patent law reforms and the use of TRIPS flexibilities given that the majority of medicines listed in the World Health Organization's (WHO) Essential Medicines List (EML) are off patent is misleading and problematic. The EML is chosen based upon "disease prevalence, evidence of efficacy, safety, and comparative cost-effectiveness" and must be "at prices individuals and the community can afford" (WHO, 2013b). Many critical medicines are not included in the EML given their unaffordability; if cost were no barrier many additional medicines would be included. Countries must not be restricted from using the legal safeguards allowed to them in the system aimed at improving public health outcomes on all medicines, not just EML medicines (Balasubramaniam, 2014).

This paper has presented evidence in response to inaccurate assumptions regarding the intellectual property system. The evidence highlights how South Africa's current intellectual property system allows exploitation by foreign companies whilst impeding the growth of our local industry. Additionally, the document shows that there is little evidence to back up industry claims that the adoption of public health safeguards in South Africa will undermine the development of future medicines. R&D MNCs have systematically evaded investing in needs driven innovation for neglected diseases and developing country disease burdens, while simultaneously forcing developing countries to uphold patents blocking access to life-saving medicines. Furthermore, industry's claim that R&D will become unaffordable if South Africa adopts public health safeguards is shameful in light of the massive profits that they annually recoup and the minimal percentage of revenue that is spent on R&D.

Finally, it is worth stating that nothing in the proposed reforms to South Africa's Patent Act will do a way with patents. Truly innovative new treatments will still be patentable. Instead, what the 'Fix the Patent Laws' campaign seeks is a more rational patent regime that takes into account South Africa's health, developmental, social and economic needs and that is based on relevant evidence rather than ideology.

Note: You can access the TAC's joint submission of recommendations, together with SECTION27 and MSF, to the Department of Trade and Industry's proposed reforms here: http://www.fixthepatentlaws.org/?p=764

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