

MYTH-BUSTER

This is a Treatment Action Campaign (TAC) paper outlining a series of ‘myths’ perpetuated by the pharmaceutical industry and other opponents of pro-public health reform. All of these can be shown to be false. The aim of this paper is to dispel these myths.

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 countries) – 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): Foreign 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) launched the Fix the Patent Laws campaign with Médecins Sans Frontières (MSF) in 2011. The campaign aims to draw attention to problems with South Africa’s national patent laws that negatively impact upon access to affordable medicines.

The purpose of this mythbuster is to respond to a number of claims that have been made by the international pharmaceutical industry - seeking to protect their business interests – in response to the Fix the Patent Laws campaign. The paper clarifies that adopting TRIPS safeguards will not only benefit public health efforts, but also local industry and economic development. Additionally, the paper highlights the flaws in pharma’s claim that protecting health in South Africa will inhibit the development of future medicines.

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MYTH 1: Strong intellectual property protection stimulates foreign direct investment; therefore, introducing safeguards to protect health will reduce future economic investment.

In 1994, WTO member countries 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.

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).

Finally, 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).

MYTH 2: Strengthening intellectual property will stimulate 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 multiple 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).

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 (Frost & Sullivan, 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 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.

Finally, strict IP protection not only impedes the growth of local industry, but also contributes to the country's trade deficit. South Africa's Department of Trade and Industry has raised 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.

MYTH 3: Incorporating public health safeguards into intellectual property laws will inhibit 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 (KEI, 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).

Moreover, R&D 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 finances the earliest, most risky stages of development (Røttingen J-A, 2013).

For example, 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 (KEI, 2013).

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. 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 generated a vast unmet need for disease areas that affect patients who are too poor or too few to guarantee large scale profits. For example, tuberculosis, a disease almost entirely faced by poorer communities, continues to be treated by medicines developed in the 1960s. 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 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.

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' and a 2008 enquiry by the European Commission found that R&D MNCs are increasingly using evergreening strategies to block generic medicines from entering the market.

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 patents that provide no new innovation or therapeutic benefit.

Lastly, patents 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 drug development from occurring. 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.

This myth buster has presented evidence in response to the common claims made by the pharmaceutical industry. The evidence highlights how South Africa's current intellectual property system allows exploitation by foreign companies while impeding the growth of our local industry. Additionally, the document shows that there is little evidence to back up pharma's claim 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, pharma's claim that R&D will become unaffordable if South Africa adopts health safeguards is shameful in light of the massive profits that they annually recoup.

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