News bites

International

Preventing abusive drug patenting: India's lessons for SA

The landmark decision by the Indian Supreme Court in Delhi to uphold India's Patents Act in the face of the 7-year challenge by Swiss pharmaceutical company Novartis, is a major victory for access to affordable medicines in developing countries, says the medical humanitarian organisation Médecins Sans Frontières/Doctors Without Borders (MSF). The decision also sets a strong example for South Africa to follow as it amends its patent laws.

A section of India's patent law prevents companies from gaining patents on modifications to existing drugs, in order to extend monopolies. Novartis filed suit against the law in 2006, in order to gain greater patent protection for a mesylate salt form of its cancer drug, imatinib (branded as Gleevec), but lost the initial case in an Indian High Court. By upholding this decision and the legality of Section 3(d), the Indian Supreme Court has verified that India can reject frivolous patent applications and, as a result, keep providing affordable Indian generic medicines to patients in developing countries.

The Novartis ruling is critically important for South Africa, as the Department of Trade and Industry (DTI) is currently drafting amendments to the country's outdated patent laws. While India has weathered an intense legal battle to maintain its critical approach for granting patents, South Africa's patent system does not include protections like India's Section 3(d) at all. Instead, South Africa allows companies to easily register patents and extend monopolies through minor drug modifications. Says Julia Hill of MSF's Access Campaign in Johannesburg: 'South Africans are missing out on affordable versions of life-saving medicines because generic competition is blocked by frivolous patents that prevent or delay generic competition.' While India avoided patenting imatinib, South Africa granted Novartis an initial patent on imatinib in 1993, which expired last month. However, secondary patents granted by South Africa, including one on imatinib mesylate salts, extend Novartis' monopoly until 2022. As a result, treating a patient with imatinib for a year in SA costs $33 896 (R312 234) – 259 times more expensive than the least expensive Indian generic alternative.

Maintaining high prices on certain medicines through secondary patent monopolies blocks access for South Africans and for the Department of Health. Unnecessarily high drug prices drive up medical aid rates and impoverish people with life-threatening illnesses. In the public sector some drugs are being rationed because of unnecessarily high prices. The Indian Supreme Court decision confirms that Indian patent law meets international standards. South Africa could implement similar rules without violating international trade rules – just like India did in 2005 when it amended patent law in 2005 to comply with World Trade Organization (WTO) requirements, but kept provisions such as Section 3(d) to keep companies from abusing the patent system.

MDR-TB: New online treatment training from WMA

The World Medical Association has announced the creation of a new application for tablet computers that will allow physicians to access a training course on the treatment of multidrug-resistant tuberculosis (MDR-TB). The application, created by the WMA and the New Jersey Medical School Global Tuberculosis Institute, gives physicians the flexibility to access the course material at any time, even when they are discussing treatment options with their patients. The application was developed in collaboration with the World Health Organization with financial support from the Eli Lilly MDR-TB partnership.

Dr Otmar Kloiber, Secretary-General of the WMA, said: 'This is a very exciting development and will enable physicians around the globe to improve their knowledge and skills in detecting and caring for MDR-TB patients without the need to plug into the Internet. The fact that the course is portable and can be accessed offline should be of enormous benefit, particularly to physicians working in poorer parts of the world where the majority of TB cases are.' He said MDR-TB was difficult to treat and represented a significant global health challenge. Despite the abundance of available knowledge on the disease, including WHO comprehensive guidelines on how to prevent, treat and control MDR-TB, translating knowledge into practice had proved to be difficult. It was because of this concern that the WMA launched some years ago a refresher course as a free online tool for physicians to learn and test their knowledge. Enabling physicians now to access this clinical care information on tablet computers offline was a huge step forward. The new application contains the

eight training modules which comprise the WMA's course on MDR-TB. It is intended as an introduction to MDR-TB management and is consistent with the principles of the WHO Stop TB Strategy. The application, which will be accessible from the Google and iPhone app webpages, will be available on 10-inch screen tablets as well as smaller displays, including smartphones, and is being released for the Android platform. The Apple iPad version will also be available shortly.

Africa

Focus on drug resistance in TB and malaria at upcoming congress

The looming threat of antibiotic-resistant strains of deadly diseases such as TB and malaria is a pivotal issue which will be discussed at the upcoming Africa Health Congress and Exhibition taking place at the Gallagher Convention Centre in Midrand from 7 to 9 May 2013. Now in its third year, Africa Health is a major 3-day conference and exhibition that brings together healthcare practitioners from around the world to discuss issues pertaining to healthcare within the African continent and features medical innovations from international manufacturers.

While many parts of Africa are coming to terms with the possibility of TB which is immune to the effects of the current generation of antibiotics, many in Europe are dealing with the continuing growth of hospital-borne pathogens which resist many conventional treatments. Additionally, there is growing research into human immunity and vital work is being done with those who have natural immunity or resistance to emerging illnesses.

The Africa Health panel of experts will offer delegates a 2-day CP-accredited review designed to provide up-to-date information on diagnosing, treating and preventing a wide range of infectious diseases throughout the African continent at the 3rd Pan African Infectious Diseases Conference. 'One of the most promising fields of scientific research is the focus on people who show immunity and resistance to emerging illnesses. The challenge we're facing is that some infectious diseases like TB are becoming more difficult to treat. During the 1930s, dedicated sanitaria and invasive surgery were commonly prescribed for those with the infection – usually caused by *Mycobacterium tuberculosis* – which is the most successful human pathogen of all time,' says Gavin Churchyard, Founder and Chief Executive Officer, Aurum Institute for Health Research, Member of the Executive Committee, International Consortium to Respond, Effectively to the AIDS/TB Epidemic (CREATE).

TB often lies dormant with no symptoms, but in a proportion of cases, becomes active, predominantly attacking the lungs. But it can also affect the bones and nervous system, and if left untreated can be fatal. Churchyard adds, 'TB infection is developing increasing resistance around the world and diseases such as HIV have increased the risk of getting TB 20-fold. Whatever we may have once optimistically thought, TB remains inevitable, unavoidable and deeply unpleasant.' Early detection of the disease will help in addressing the TB problem and initiate the appropriate TB treatment. In recent years, new approaches to diagnosing both drug-sensitive and resistant TB have been evaluated. Diagnostic tests such as Xpert MTB/RIF and Line Probe Assays have reduced the time to diagnosis and have been shown to have good sensitivity and specificity. South Africa, one of the high-burden countries, has adopted these tests in the TB diagnostic algorithm. In other countries lack of diagnostic capacity has hampered the effective response to these improved TB assays.

To effectively address the MDR problem, countries need to scale up diagnostic services and similarly scale up treatment services. This should be implemented in combination with other strategies such as initiating antiretroviral therapy in HIV-infected individuals and isoniazid preventive therapy among HIV-infected individual who do not have TB.

The Pan African Infectious Diseases conference contains international research papers, looking at a broad range of issues, from the risk of TB after seroconversion to HIV infection, to the impact of ethnicity on the pattern of disease.

South Africa

Competition Commission probe into private healthcare 'overdue'

The high costs of private hospitals and the three companies that manage most of the country's 97 medical aid schemes will almost certainly be scrutinised by the Competition Commission, says healthcare economist Nicola Theron, managing director of research company Econex. Last year it was announced that the commission would investigate private healthcare costs. On 1 April a provision in the Competition Amendment Act came into effect, granting the commission the power to conduct a healthcare pricing inquiry and subpoena witnesses. Private hospital prices increased by 300% between 1994 and 2010, says Theron. Three hospital groups – Life Healthcare, Netcare and Medi-Clinic – hold 85% of the market. Although the commission has allowed the hospitals to merge, it has expressed concern that the consolidation of the three main players has reduced competition in the sector. Healthcare economist and Wits Social Chair Professor Alex van den Heever also blamed the rising hospital costs on the lack of competition. 'The hospital groups do not compete on cost, quality or

efficiency. They never have and the situation has deteriorated,' he added. A Board of Healthcare Funders (BHF) spokesperson, Heidi Kruger, labelled the three groups 'an oligopoly'. 'That's why they can charge what they like.'

NHI a critical consideration in policy changes

The government wants to reduce the prices of private healthcare as it hopes to contract private facilities for the public sector as part of the roll-out of the National Health Insurance. South African Medical Association chairman Dr Mzukisi Grootboom said that although private healthcare in South Africa cost far more than public healthcare, it was not expensive by international standards. However, Grootboom agrees with research showing that private hospitals and the administrative costs of managing medical aid schemes are responsible for rising prices. If the commission discovers anti-competitive practices, it will have the power to refer those responsible to the Competition Tribunal that can set fines. The competition commission can also suggest policy changes to the Department of Health. Hospital Association of Southern Africa spokesman, Dumisani Bomela, said more people were using private hospitals more often, leading to increased expenditure on private hospitals.

The BHF anticipates the Commission's added powers will result in robust scrutiny of the industry. Says BHF MD, Dr Zokufa: 'There is currently no transparency in the pricing of healthcare services, and a lack of scientific approach in arriving at tariffs. These and other cost-drivers within the industry need to be curtailed through reform'. The BHF believes that one of the most significant drivers of costs within the sector resulted from the Competition Commissioner's 2004 ruling which outlawed collective bargaining in the private healthcare arena. This resulted in massive increases in costs within the sector. Collective bargaining in the medical schemes environment gave consumers more power to negotiate better prices for healthcare, which therefore resulted in a downward pressure on costs. The BHF therefore anticipates that one of the outcomes of the enquiry will be the ability for funders to come together to negotiate collectively again, in the interest of the consumer. 'We hope that this market enquiry will delve into all aspects of pricing within the environment and that the necessary reform will follow so that our world-class private sector may become more affordable to more of the population, and that the private sector can position itself to become an integral part of the proposed NHI,' says Zokufa.

DSPs and PPNs – profits beating quality care?

The Health Professions Council of South Africa (HPCSA) has noted the practice of enticing practitioners to enter into Designated Service Provider (DSP) and Preferred Provider Network (PPN) contracts with medical aid schemes. While these schemes are not illegal *per se*, the HPCSA is concerned about the potential ethical transgressions that may arise from practitioners entering into these agreements with schemes. DSP and PPN agreements take varied forms, but are basically when a practitioner enters into an agreement with a medical aid scheme, which results in direct payment and being listed as a preferred service provider. The HPCSA's concern is that schemes in certain instances exert pressure on medical practitioners to prescribe certain medication or take certain decisions on behalf of patients who will benefit the scheme and not necessarily the patient and/or make clinical decisions aimed at cost-cutting. The HPCSA reminds healthcare practitioners of their obligation to always act within the best interests of their patients and to desist from entering into any arrangements that may result in the quality of clinical care being compromised. The HPCSA has already consulted with the South African Medical Association (SAMA) and 'together we have outlined concerns where these ethical problems may arise – SAMA has been very proactive and positive in addressing these issues with their members and the Council appreciates all these efforts,' a spokesman added.

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SINGLE SUTURE

Anti-doping agency warns athletes of black market drug

Drug cheats watch out. The World Anti-Doping Agency (WADA) has taken the rare step of issuing a warning to athletes after discovering abuse of a black market drug that causes multiple cancers in rodents.

The drug, called GW501516, was originally developed by pharmaceutical company GlaxoSmithKline (GSK) to stimulate muscles to burn fats instead of sugars, in order to raise levels of 'good' cholesterol. However, the company abandoned further development in 2006 after tests on rats showed that at all doses, the drug rapidly causes cancers in a multitude of organs, including the liver, bladder, stomach, skin, thyroid, tongue, testes, ovaries and womb. 'GSK does not manufacture it or authorise its sale,' says a company spokesman.

In 2009, GSK warned WADA of the potential risks of abuse of the drug, and the agency added the drug to its list of prohibited substances that year.

The drug is openly promoted on websites for bodybuilders and athletes.

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