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Patent wars: affordable medicines versus intellectual property rights

In the battle for affordable medicine India has delivered several blows to the drug industry. **Jacqui Wise** reports on how India has inspired other developing countries to challenge the patent system

The pharmaceutical industry is increasingly looking towards emerging markets, where demand for new drugs is rising rapidly alongside rates of chronic disease. But in recent years India, known as the “pharmacy of the developing world,” has led the battle for affordable drugs, using legal mechanisms to overturn patents so that its generic drug companies (which produce a fifth of the world's generic drugs) can undercut the Western giants. Developing countries have followed India's example, and battles over patent protection and prices have broken out from Indonesia to Brazil.

The fight echoes the one over access to treatments for HIV infection a decade or two ago, but it is now being fought over a far wider range of drugs with greater financial implications for Western drug companies.

In a series of high profile court cases, India has rejected several patent claims for cancer drugs and Roche decided in August not to pursue a patent application for its breast cancer drug trastuzumab (Herceptin) because it viewed it as a losing battle in India's current intellectual property environment.^{1 2}

Public health arguments

A key decision came in 2012, when India issued a compulsory licence for Bayer's cancer drug sorafenib (Nexavar), allowing a local company Natco to produce a generic version.³ A compulsory licence allows a company to produce a patented product without the consent of the patent owner. Under the World Trade Organization's trade related aspects of intellectual property rights (TRIPS) agreement countries are free to grant compulsory licences in the interest of public health; however, there is much argument about how this is defined. The Indian courts ruled that the costs of \$4500 (£2700; €3300) a month for sorafenib were unaffordable to the Indian government. A generic version of the drug is now available for \$175 a month.

INDIA'S FIGHT FOR AFFORDABLE DRUGS

2001: The Doha declaration on trade related aspects of intellectual property rights (TRIPS) and public health reaffirmed the right to balance public health needs with intellectual property rights

2001: Indian generic company Cipla begins marketing a \$1 a day generic combination antiretroviral therapy

2005: India signs the World Trade Organization's TRIPS agreement, which includes a 20 year patent term for medicines

March 2012: India awards first compulsory licence for a generic version of Bayer's cancer drug sorafenib (Nexavar)

April 2013: Indian Supreme Court rules against Novartis, ending seven year battle to patent an updated version of leukaemia drug imatinib

May 2013: India put on the Office of the US Trade Representative's priority watch list

August 2013: Roche decides not to pursue its patent on trastuzumab (Herceptin)



Since that decision a further two applications for compulsory licences have been rejected. But the Indian government has set up an expert committee to review drug patents and identify whether any additional compulsory licences should be issued.⁴ The drug industry fears that the floodgates will open and that this will create an “innovation crisis.” Andrew Jenner, executive director of the International Federation of Pharmaceutical Manufacturers and Associations, said: “Increased use of compulsory licensing provisions will reduce the incentive to

invest in the research and development of new medicines in India and should be seen as a last resort as open discussions with patent holders often lead to successful outcomes.”

Widening attack

India is not the only country issuing compulsory licences and rejecting patent applications. In 2012 Indonesia issued compulsory licences to over-ride the patents on seven hepatitis B and HIV treatments. In Thailand compulsory licences have mainly been issued for HIV drugs but it also



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issued three compulsory licences in 2007-08 for cancer treatments.

In 2012 China overhauled parts of its intellectual property laws to allow compulsory licensing. It was speculated that it would issue its first compulsory licence for tenofovir, Gilead’s drug for HIV and hepatitis B. Anticipating this, the manufacturer reduced tenofovir’s price, but it was not enough and last year the Chinese State Intellectual Property Office revoked the drug’s patent saying it lacked novelty. In 2008 the Philippines brought in the Universally Accessible Cheaper and Quality Medicines Act, which also includes measures to grant compulsory licences. So far none has been issued, however. Brazil is currently amending its patent laws. A parliamentary committee report in October recommended stricter rules for what deserves a patent and the right to issue compulsory licences. The report recommends that an independent government body vetoes patent applications if the drug does not meet certain standards of innovation.⁵

South Africa is also reforming its patent laws. Under its current system South Africa grants far more patents than other countries with the result that it pays up to 35 times more for branded drugs than some other countries do, according to Médecins Sans Frontières.

US fights back

The pharmaceutical industry in the United States is lobbying hard over what it sees as India’s growing non-recognition of intellectual property rights. The US government has responded by putting political pressure on India. A report released last year by the Office of the United States Trade Representative placed India on the priority watch list for failing to uphold international drug company patents.⁶ It said that it would “monitor closely” developments concerning compulsory licensing, which it described as a “troubling precedent.”⁷ Other countries placed on the list for failing to protect intellectual property rights include Algeria, China, Indonesia, and Thailand. The Global Intellectual Property Center of the US Chamber of Commerce also last year introduced a new index ranking 11 countries on the strength of their intellectual property rights systems, with the US ranked highest and India ranked lowest.⁸ The US is also putting pressure on 11 Pacific Rim countries to sign up to the Trans-Pacific

Partnership agreement.⁹ This is currently being negotiated in secret but is understood to include intellectual property clauses that would restrict access to affordable generic medicines.

The patent system allows drug companies to charge high prices for drugs for a limited time in order to recoup their research and development costs. And drug companies are not the only ones warning that their ability to invest in research and development will be seriously damaged if they lose this source of revenue. An independent report from the UCL School of Pharmacy argues that without intellectual property rights private investment in high risk biomedical research would be unlikely.¹⁰

David Taylor, professor of pharmaceutical and public health policy at University College London and author of a recent report, *Health and Health Care in India*, also argues that countries such as India should spend more on healthcare and improving access to medicines. India spends only 1.2% of its gross domestic product on pub-

Drug patents cause fresh spat between South Africa and industry

An embarrassing leak of the drug industry’s lobbying plans against patent reforms has led to cries of “genocide” from South Africa’s health minister. **Andrew Jack** reports from Cape Town

Nearly 15 years after the pharmaceutical industry was accused of unwisely picking a fight with Nelson Mandela over affordable access to medicines, it is at the centre of a fresh spat concerning patents in South Africa.

Last month, Aaron Motsoaledi, the health minister, accused drug companies of “genocide” after seeing their plans to campaign against draft government proposals on intellectual property reforms. “This document can sentence many South Africans to death,” he told the *Mail & Guardian*.¹

The inflammatory rhetoric has made industry executives and even some activists squirm, yet it comes against the backdrop of spring elections in which the ruling African National Congress is fighting to retain its political dominance.

It also reflects a broader international battle over intellectual property rights, pitching industry claims that tougher patent rules will encourage investment and innovation against patient organisations, which argue that they restrict competition and keep prices unaffordably high.

The latest feud has already had repercussions for industry, with Novo Nordisk, the Danish diabetes focused drug company, and Roche of Switzerland both resigning their membership of the Innovative Pharmaceutical Association of South Africa (Ipsa), the industry trade body.

The reason for Motsoaledi’s comments was a

leak in the local media of plans for a \$600 000 (£370 000; €440 000) lobbying “campaign to prevent damage to innovation” during 2014 on behalf of Ipsa and PhRMA, the US drug company association.²

Motsoaledi’s reaction recalled the conflict at the turn of the century, when similar battles over patents in the South African courts spilled into a vocal debate over affordable access to antiretroviral medicines for HIV, in a country with one of the highest prevalences and—at the time—lowest treatment rates.

Public Affairs Engagement (PAE), a US lobbying firm, argued in its document submitted to Ipsa that: “South Africa is now ground zero for the debate on the value of strong IP [intellectual property] protection.” It claimed that recent government proposals would undermine investment and fail to tackle the reasons it saw as explaining the poor health system: “substandard public health policy, an inadequate delivery system and poverty.”

Its pitch followed publication by the country’s Department of Trade and Industry last September of a long awaited set of proposals that includes compulsory licensing to overturn patents, parallel imports (the import of

“South Africa is now ground zero for the debate on the value of strong IP [intellectual property] protection”

licly funded healthcare, a lower figure than most other comparable countries, the report points out.¹¹ Taylor argues that the country's focus on new anticancer drugs that can be used only in high technology settings is the wrong approach and will mainly benefit richer patients while many people do not have assured access to the most basic treatments.

"There is a widespread belief in India that new anticancer drugs can cure cancers, although what is needed is more investment in preventive measures against tobacco related harm and cancers caused by infections," he said.

Questions over costs

Others suggest that industry spends far less than it claims on research and development. The drug industry claims the cost of each successful innovation is \$1bn to \$2bn. But Donald Light, network fellow at the Edmond J Safra Center for Ethics at Harvard University and a professor at Rowan University, calculates that when inflators are removed from the industry's principal dataset costs average around \$100m per product.¹²

Leena Menghaney, a lawyer and spokesperson for Médecins Sans Frontières in India, said that she didn't dispute that research and development cost money. "But pharmaceutical com-

panies won't reveal what they spend on R and D so we can't determine if the price is fair or not. And even when they are earning huge profits they continue to price drugs out of reach. They choose the low volume high profitability model over high volume low profitability."

She cites the \$70 000-80 000 cost for a three month course of the new hepatitis C treatment sofosbuvir, which was approved by the US Food and Drug Administration in December. "Such insanely high prices are an issue even for developed countries," she says.

Light also says that over the past 30 years patent law has become increasingly loose, with an ever widening set of criteria. "Patents can be granted on new formulations, such as moving from a pill to an injection or to a combination," he explains. Light says 95% of new drugs licensed by the European Medicines Agency or the FDA are judged by independent review teams of physicians as having little or no advantage for patients. "What India wants to do is redraw the line so that a patent is only granted on new molecules and clinically superior drugs. This would be better not only for patients in India but also those in the UK, Europe, and the US."

But Jenner, from the International Federation of Pharmaceutical Manufacturers and Associa-

tions, counters: "Innovation is a continual process. Incremental innovation delivers changes to medicines, such as better tolerability and improved dosing, that are often critical to better care, and these advancements are recognised by the vast majority of patent systems around the world."

New approaches are also being proposed to diffuse the patent row. Light favours a prize based system to encourage the development of new medicines in high priority areas. Another approach is a wholesale system of differential pricing, with companies charging less in poorer regions of the world than in richer ones. This already happens to some extent, with companies such as GlaxoSmithKline leading the way. The problem is that there can be "leakage" of lower priced drugs into wealthier countries. And people in wealthier countries are starting to complain that they are paying far higher prices than patients in other countries.¹³

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medicines from other countries where they are sold more cheaply, usually from pharmacies rather than manufacturers), more detailed scrutiny of patent applications, and a switch in responsibility to companies to defend any patent challenges.³

Industry executives expressed frustration that the government had refused to discuss the proposals. They also argued that the proposals sat awkwardly with a separate innovation policy document issued in January by the Department of Science and Technology.⁴

Some local non-governmental organisations, including Médecins sans Frontières, the Treatment Action Campaign, and Section 27, point out that some of the new proposals merely reiterate the current legal position (including the legality of compulsory licences under World Trade Organisation rules) or bring South Africa into line with other countries (such as the higher level preapproval scrutiny of patents in Europe and the US).

They point out that the current intellectual property rules—which industry believes would be weakened by the current proposals—have not led to significant increases in investment in local research or manufacture.

Industry tactics

There was nothing illegal in the PAE lobbying pitch, but it provided an unusual insight into

lobbying tactics. The consultancy planned to create a new alliance called Forward South Africa to be led by "a respected former government official, business leader, or academic."

The alliance would in turn fund an academic paper "commissioned by independent institutions" to make the case for the importance of strong intellectual property rights in "encouraging wealth." There would be opinion articles in the media and efforts to "amplify the voices of development experts."

An accompanying leaked email from the head of the South African subsidiary of Merck in the US to his local counterparts, said that PAE had been selected to run the campaign, with the aim of rapid implementation to delay the government's proposals until after the elections.

Drug company executives in Europe and the US have since tried to distance themselves from the PAE campaign, arguing that they had not approved it and would not do so.

They have been embarrassed by the leaks, particularly since some companies have separately been examining a broader series of potential reforms designed to improve affordability and access to medicines in lower income countries, with plans to arrange pilot programmes to test different models.

The tensions are acute at a time when industry is keen to expand into emerging markets,



Aaron Motsoaledi, health minister

notably countries like South Africa where there is growing demand for medicines from middle class consumers. Yet growing pressure for a more widespread, equitable health system is fuelling continued concerns over affordability.

Whether or not a lobbying campaign proceeds in South Africa, industry executives locally will be hoping that the government delays any final decision on patent revisions until after the volatile election period. But the debate of ideas has already been escalated far beyond the control of the local subsidiaries. It resonates around the world.

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