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Agriculture	By Priti Radhakrishnan						
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Human Rights	As India begins to use new generations of ARV drugs, the costs will escalate thanks to strict patent regimes. The government, the Patent Office and the judiciary must start making decisions about how to curtail patent abuse and increase access to affordable HIV drugs.						
Technology							
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Population	An increasing number of HIV-positive people in India urgently require access to antiretroviral drugs (ARVs). ARVs have a proven history of delaying the development of HIV into AIDS. As of 2008, around 2.4 million Indians live with HIV, and approximately 100,000 of these individuals are currently receiving ARVs. Some 450,000 people in India currently require ARVs, and this number is expected to grow significantly in the coming years. Across the world, the figures are staggering: 10 million people are estimated to require access to ARVs, with roughly 3 million actually receiving the drugs. ¹						
Poverty							
Disasters							
Trade & Development	Access to ARVs is a matter of life and death. The lack of access to affordable ARVs remains a problem and was extensively discussed at the 2008 International AIDS Conference in Mexico. The concerns around access to ARVs have recently become more acute. This is because India, a major provider of generic ARVs to low-and middle-income countries around the world, now has to balance having a patent law covering medicines (for the first time in nearly 35 years) with providing access to low-cost treatment to the world's poor. Decisions made in India regarding patent enforcement will have a profound effect on millions of people living with HIV in India and globally.						
Right to Information							
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Disabilities	Strict patent regimes are a factor in causing high prices for, and limited access to, ARVs. Flexible patent regimes, with provisions to safeguard public health, can help ensure significant price reductions and greater access to life-saving ARVs. Indian policymakers should pay attention to how stark differences in the purchase price of ARVs worldwide are directly attributable to the approaches taken on patent laws.						
Corporate Responsibility							
HIV/AIDS							
	India's patent law						
	India only began reviewing pharmaceutical product patent applications in 2005, when it was required to become fully compliant with the World Trade Organisation's (WTO) trade agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). At that time, as a public health safeguard, India included a unique provision (section 3(d)) to the Indian patent regime.						
	Section 3(d), popularly known as the "efficacy" standard, prohibits the patenting of new forms of existing pharmaceutical substances that do not demonstrate significantly enhanced efficacy. This was intended to prevent companies from attempting to obtain follow-on patents for minor improvements to an existing patent before it expires. If these companies are successful, it results in the exclusion of generic drugs from the market and allows for potentially exorbitantly high prices due to lack of competition.						
	While admirable in its intention, section 3(d) did not define what efficacy actually is –there are numerous pharmacological applications of the term, but no standardised universal usage -- or what a patent applicant would have to show to prove efficacy. Moreover, the concept is generally used in regulatory affairs such as whether a new drug provides benefits and can be sold to patients but is foreign to patent law. Therefore, in 2007, the Swiss pharmaceutical conglomerate Novartis challenged the efficacy provision in the Indian courts on the grounds it was unconstitutionally vague and arbitrary. The Madras High Court ultimately rejected Novartis' challenge. Novartis did not appeal the case to the Supreme Court, so the efficacy provision remains the law.						
	Yet efficacy remains undefined. The Madras High Court did imply that efficacy should be defined from a 'therapeutic' perspective. There is now an open question as to whether a formal definition of efficacy should be restricted solely to therapeutic efficacy, or should also include manufacturing, stability, or delivery mechanism efficacies. Although the government and the courts have not provided any clear definitions of efficacy to date, the actual case ² on Gleevec's patentability is set to be heard soon, and a definition could be given by the Intellectual Property Appellate Board.						
	The confused state of the current law						
	Without clear direction on the efficacy standard, each new patent will be fought over in the Indian Patent Office and in the courts on a case-by-case basis, potentially delaying access to vital medicines, as well as creating conflicting standards. For example, two years ago, civil society groups challenged the drug maker Boehringer Ingelheim (BI) over its patent application for a pediatric syrup version of the HIV drug Nevirapine.						
	BI claimed its new formulation of the existing drug met the efficacy standard because the syrup version allows the drug to be ingested by children living with HIV who were unable to swallow the prior tablet version.						
	The Indian Patent Office denied the patent on the grounds that newer forms of known drugs must show therapeutic efficacy in order to be granted a patent—that is, they must be clinically more beneficial as a drug, not just a new method of delivery. As this is the first decision from the Patent Office on the 13 patent oppositions filed by public health groups against various HIV drugs, it could set an important precedent for the pending patent applications.						
	However, the Patent Office's ruling still leaves many questions unanswered: what type of drug development is considered an important improvement, and what will prevent the abuse that Parliament tried to address through section 3(d)? When comparing the newer form (like the Nevirapine syrup) to an older form of the drug, which older form do you measure it against? What happens when there is some overlap between the new method of delivery and an increased potency of the drug in that form? When do these technical determinations cross the line into the arena of policy directives?						
	Two contrasting approaches: Mexico vs Brazil & Thailand						
	The status quo in India as to pharmaceutical patents has changed for the long-term. It is no longer possible, because of India's obligations under TRIPS, to retain the unrestricted environment that existed until 2005. Instead, the government will need to act decisively by defining key legal provisions, granting compulsory licences where appropriate, seeking voluntary licences from private companies to engage in public manufacturing to meet domestic needs, and/or purchasing drugs themselves to resolve health crises.						
							<ul style="list-style-type: none"> • Access to anti-retrovirals (ARVs) in India: Patents and the way forward • 2031 Outlook: More promises • How ART survival rates compare in developing countries • Injecting drug users deprived of treatment • The Invisible Men • 'HIV/AIDS is not taking money away from other diseases': Sujata Rao • Still a long way to go: Overview of the UN High Level Meeting on HIV/AIDS • Call for action on HIV TB • The National AIDS Control Programme (1, 2, 3)

When making such important policy decisions regarding patent law, the Indian government can take note of examples of other countries. Mexico, for example, adopted very strict patent laws. The enforcement of patent rights in Mexico allows little scope to safeguard public access to ARVs. Mexico does not even permit compulsory licensing on drugs when the prices are too high or anti-competitive behaviour exists. Mexico also does not allow for licensing for the government's own use, eg, for free distribution through public hospitals for low-income communities.

Consequently, the Mexican market is dominated by transnational companies that maintain market dominance through lobbying and negotiations. The Mexican generics industry has not been able to get manufacturing capacities up to competitive levels. As a result, prices remain exorbitantly high: Mexico is paying \$2000/pppy (per patient per year) for 3TC, compared to low-income countries paying \$35/pppy. The Mexican experience cautions against adopting or implementing patent laws without safeguards for the public health, resulting in exorbitantly high ARV prices.

With its burgeoning HIV population, India cannot afford to allow ARV prices to skyrocket – the consequences would be untreated patients, or diverting resources from other pressing health needs in the country.

In contrast to Mexico, both Brazil and Thailand have taken important steps to use flexibilities available under the international frameworks of TRIPS to keep ARV prices affordable. One important tool available in India, Brazil and Thailand is compulsory licensing—where a government licenses others to produce a patented drug without the permission of the patent holder. When countries issue or threaten to issue compulsory licenses on important HIV drugs, they can achieve significant price reductions.³

- 1 The price of Efavirenz dropped from \$580 to \$170 per patient, per year when Brazil issued a compulsory licence for it last year.
- 2 Brazil also has a strong history of negotiating with patent-holders on ARVs, achieving significant price reductions on the three drugs – Efavirenz, Lopinavir/Ritonavir and Nelfinavir – that was eating up 63% of the overall ART budget.
- 3 Thailand also issued compulsory licences on Efavirenz and Lopinavir/Ritonavir in 2007, bringing down the price on Efavirenz from \$468 to \$216, and on Lopinavir/Ritonavir from \$2967/pppy to \$676/pppy.

The experiences of Brazil and Thailand teach us important lessons that India may want to pay attention to – as patents are granted on ARVs, governments are issuing compulsory licences where appropriate to meet their domestic needs. India's issuance of compulsory licences will likely be geared towards domestic production, rather than following Brazil's example of using such licences as a negotiating tool. India's robust generics industry is best placed to meet domestic needs unlike other developing countries that have not been able to domestically produce ARVs under compulsory licence.

Industry responses to patent challenges

Once India sets a clear patent policy, pharmaceutical companies themselves will begin to censor their patent applications, relieving the stress on the Patent Office and the courts. Several recent cases illustrate clearly that pharmaceutical companies' behaviour can change when they perceive strong opposition to their patents.

- 1 In 2007, just a year after civil society challenged the validity of the drug patent on Abacavir, Glaxo SmithKline (GSK) announced the withdrawal of its ARV patent application on Abacavir. Shortly thereafter, GSK also announced a 31% price reduction for low-income countries, in anticipation of increased generic competition as a result of the patent withdrawal.

In the Abacavir case, civil society argued that Abacavir could not meet the 'efficacy' standard under the law. Once there is a clear definition of the 'efficacy' standard, more companies may recognise their drugs may not meet the standard, and voluntarily withdraw the patent application, enabling more competition, and resulting in greater access and price reductions.

- 2 Civil society and CIPLA filed two sets of oppositions on Gilead Sciences' patent applications for the drug Tenofovir. The applications are still pending but soon after the challenges were filed, Gilead Sciences issued several voluntary licences with low royalty rates, improving access to this important drug. Clearly then, pharmaceutical companies anticipating resistance or threats to their patents will themselves voluntarily provide greater access to medicines.

An important consequence of patent withdrawals in India is the effect on these related patents all over the world. For example, following the patent oppositions against Tenofovir in India, the US non-governmental organisation PUBPAT challenged the patents in the US, resulting in preliminary rejections on the Tenofovir patents. Brazil has also followed suit, rejecting the Tenofovir patent, resulting in potential cost savings of \$30 million/year to its national AIDS programme.

Conclusion

The direction India takes on its patent law will have a profound impact on access to HIV drugs for millions of people in India and across the world. Therefore, the need for a clear definition of the 'efficacy' standard is an issue of growing urgency and importance. When section 3(d) was enacted, the government could have, through the statute, defined 'efficacy' and thus set a patent policy. However, the government did not do so. The Indian Patent Office then had an opportunity to provide definitions of 'efficacy' in its manual, but also failed to do so. Consequently, it has now fallen to individual patent examiners in each of the four patent offices to determine on a case-by-case basis whether new patents for existing drugs meet the 'efficacy' standard. But since they are not bound by each other's decisions, the cases lack uniformity of principle or rationale. This lack of uniformity will result in appeals to the judiciary. Once the judiciary (either a high court or the Supreme Court) begins interpreting the statute, its definition could become law.

For now, because the patents for ARVs are for drugs filed between 1995-2005, patent examiners can decide the cases on a purely technical basis. For these 'mailbox' drugs, the patent applicants (drug companies) can submit clinical data to prove efficacy. There is potentially documentation of the drug and its effects in both its current and previous versions.

However, this will not be the case for the newer generation of ARVs. Whereas data is required to prove efficacy for the older generation of drugs, the patent applications for the newer drugs have to be filed before clinical trials or other scientific tests are conducted, when no data is available. When civil society and generic manufacturers lack actual data to challenge a patent under the 'efficacy' standard, the result is that newer ARVs such as Maraviroc, Raltegravir and Etravirine have been granted patents. This is turn could result in reduced access and higher prices for this next generation of drugs. The World Health Organisation estimates that by 2010 approximately 90% of global ARV costs will be attributed to second-line ARVs.⁴ India is still slowly introducing second-line ARVs into its ARV programme and it remains to be seen how the government will ensure access to this newer – and more expensive – generation of drugs.

India cannot continue to wait for third-party actors such as civil society and generics suppliers to file cases and ensure access to ARVs for its citizens. As the HIV crisis continues to escalate, patients cannot continue to be denied access to life-saving drugs. The burden on people living with HIV and on the Indian government's own health resources will be unbearable if prices escalate. The government, the Patent Office and the judiciary must start making decisions about how to curtail patent abuses and increase access to affordable HIV drugs.

Several existing mechanisms within the patent law can be utilised to increase access. When the time comes, the government may either seek compulsory licensing or encourage voluntary licensing. As we have seen from other countries, even the threat of compulsory licensing is enough to cause ARV prices to drop dramatically. Yet India may not have to make this threat for its domestic programme, for the government has the legal authority to issue licences for its own public sector ARV programme. Either way, the Indian government should evaluate the legal cases happening at home, as well as the impact of patent law on access to ARVs in other countries, and develop a strong policy to ensure access to HIV drugs going forward.

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Endnotes

1. http://www.who.int/hiv/data/art_table_2007.png
2. This case centres on the patentability of the cancer drug imatinib mesylate (known by the brand name Gleevec). In January 2006, the Chennai Patent Office rejected the patent application for this drug, citing amongst other reasons the lack of inventiveness and efficacy. Novartis has appealed this decision. This is a separate case from the high court case challenging the constitutionality of the efficacy provision itself.
3. These figures are summarised in the article 'Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand', Ford et al., AIDS 2007, Vol 21, Suppl 4.
http://www.who.int/entity/hiv/pub/meetingreports/second_line_art_report_2008.pdf.

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