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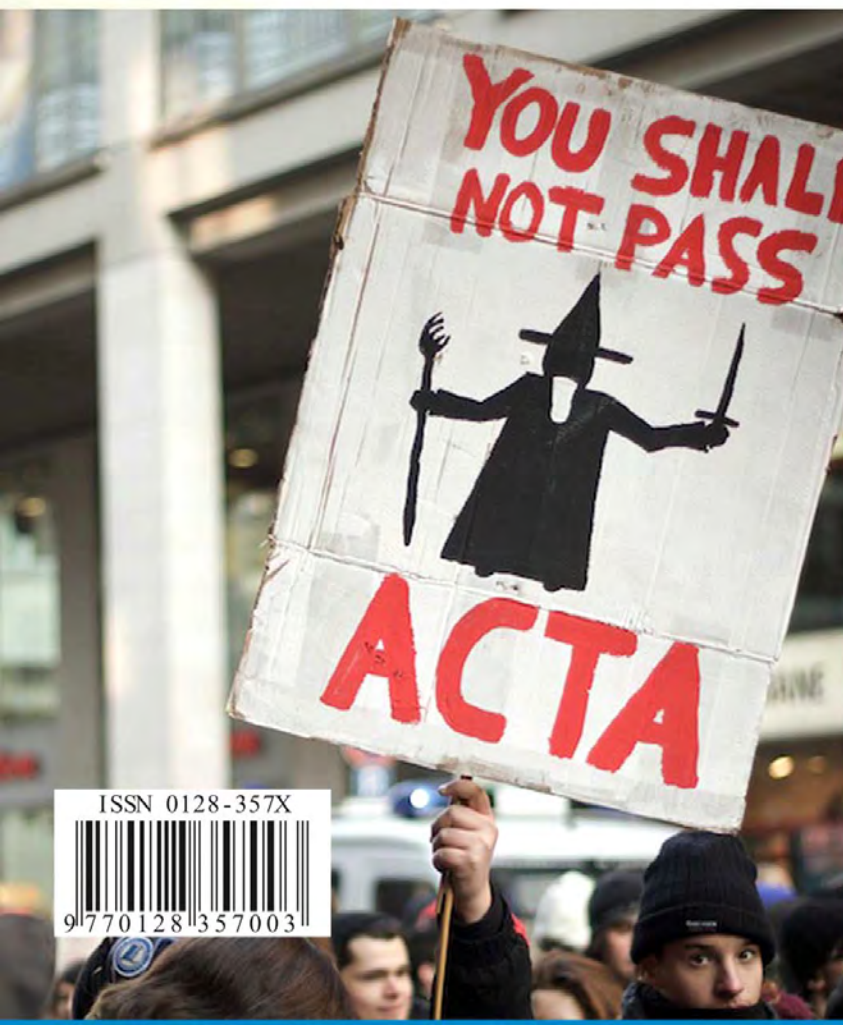
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Generics under threat

Access to affordable medicines in jeopardy



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Editor's Note

THE right to health is a fundamental human right recognised by international human rights law. While the realisation of this right is dependent on many factors, a crucial precondition is access to affordable medicines.

It is generally accepted that a way to keep medicine prices within affordable limits is to permit the production of generic versions of the more expensive patented medicines.

The prospect of producing such generic medicines in any country is however subject to the country's intellectual property laws, in particular its patent regime. Stringent patent laws may, in effect, prohibit the production of generics by conferring exclusive, cast-iron protection to the originator in respect of his product. To overcome this hurdle, some developing countries, such as India, had adopted more appropriate intellectual property laws which, while affording a measure of protection to the originator, did not stifle the production of generic medicines.

Thus the Indian Patents Act which replaced the country's colonial patent regime in 1970 recognised process patents rather than product patents for pharmaceuticals. With the patent limited to the process rather than the product, the path was opened up to domestic drug manufacturers to find alternative processes to that covered by an existing patent. In this way, India was able to develop an impressive domestic pharmaceutical industry which was able to supply cheap generic medicines not only to its own people but also to much of the developing world.

The emergence of the World Trade Organisation (WTO) in 1995 however posed a major challenge to the future of the generics industry in developing countries. As a result of the pressure and influence of powerful corporations in the West, intellectual property rights had been brought within the WTO's mandate. Member states of this organisation that was ostensibly concerned with trade were obliged, under its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to amend their domestic laws to confer recognition not only to patents on processes but also to patents on the product as such. The upshot of this change was that once a new medicine came into the market, it would no longer be possible to make generic versions (even by a different process) so long as the patent was operative. Imports of generic medicines are also prohibited while patent protection exists in a country.

However, thanks to a campaign waged by international civil society and developing countries, the harsh rigours of these provisions were ameliorated by a decision taken by the WTO membership at a meeting in Doha in 2001. The Doha Declaration on the TRIPS Agreement and Public Health categorically affirmed that the Agreement 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'. This offered a lifeline to developing countries, especially those like India which have well-developed generics industries. Thus, when India finally amended its intellectual property laws in 2005 to comply

with the TRIPS Agreement, it took full advantage of the TRIPS flexibilities reaffirmed by the Doha Declaration to incorporate important safeguards in the amendments to its patent laws. In this way, it was able to ensure the continued development of its domestic medicines industry.

But new threats to the viability of generics production in developing countries have emerged in recent years which may yet undermine access to affordable medicines. The first of these has taken the form of free trade agreements (FTAs) with developed countries which compel the developing-country counter-party to accept 'TRIPS-plus' obligations, i.e., obligations which go beyond those imposed by the TRIPS Agreement. For example, the highly controversial FTA which India has been negotiating with the European Union since 2007 includes a provision which would oblige India, in certain circumstances, to offer patent protection beyond the 20 years required by the TRIPS Agreement.

Another threat facing the generics industry in developing countries has been the moves by the EU to hinder the entry of generic imports into its markets. The ploy has been to use the cover of the battle against counterfeit medicines to stigmatise and frustrate the entry of generic medicines into European markets. For example, on more than 20 occasions, customs authorities in the Netherlands, on this pretext, detained consignments of Indian-manufactured generic medicines that were in transit to developing countries. More recently, the Anti-Counterfeiting Trade Agreement (ACTA) negotiated by several countries, including the EU, has sought to extend and formalise legal sanction for such harassment. Despite strong protests by civil society activists, the agreement has already been signed by a number of EU countries.

In the case of the EU-India FTA, the final decision lies with the Indian government. As it is, the decision by India in 2001 to liberalise its policy on foreign investment in the pharmaceutical sector was a huge and costly mistake. It has resulted in a wave of takeovers of domestic drug companies by multinational corporations, whose growing dominance of the Indian pharmaceutical market has raised concern. To compound that mistake with an FTA which jettisons the remaining safeguards in India's intellectual property laws would be a catastrophe. The implications of such a foolhardy move for the Indian people and for the millions all over the developing world who are dependent on affordable generic medicines from India can hardly be fathomed.

Our cover story for this issue focuses on the Indian pharmaceutical industry and how India's role as the pharmacy of the developing world has come under threat in the new millennium. We examine the latest challenges facing the industry and highlight the crucial need for concerted action to ensure that the fundamental right to affordable medicines is not further undermined.

— *The Editors*

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A worker at a manufacturing unit of an Indian generic medicine producer. India's pharmaceutical industry, which has been called the pharmacy of the developing world for supplying affordable generic medicines to countries of the South, faces multiple challenges which may yet undermine its role. 4

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Inching towards a financial transaction tax

A recent proposal to introduce a European financial transaction tax (a tax to be levied on bond and equity transactions and on derivatives) has met with strong resistance from Britain and a number of other countries. Despite this opposition, *Peter Wahl* is optimistic that this move to curtail financial speculation cannot be indefinitely delayed.

THE tension around a financial transaction tax (FTT) was growing before the 13 March Council meeting of European Ministers of Finance (ECOFIN). Finance ministers from nine EU countries – Austria, Belgium, Finland, France, Germany, Greece, Italy, Portugal and Spain – had written a letter applying substantial pressure on the Danish presidency. In EU diplomacy such a letter is quite a strong instrument.

The letter asked for the Council's decision-making process regarding the European Commission's legislative proposal on an FTT to be speeded up before June 2012. As it was known since December 2011 that the UK would under no circumstances accept a European FTT, the proponents of the tax did not want the process to be delayed. In addition, the next two incoming presidencies, Cyprus (second half of 2012) and Ireland (first half of 2013), oppose the FTT, which would make it more difficult for the proponents to get a decision.

On 13 March, the EU-27 Ministers of Finance failed to reach consensus at the ECOFIN meeting, and this did not come as a surprise. When UK Prime Minister David Cameron visited Berlin in December, he had expressed the British opposition to the FTT in no uncertain terms. At the ECOFIN meeting the UK was joined by the Czech Republic, Ireland, Sweden, the Netherlands, Malta, Luxembourg and Cyprus.

Since EU rules require unanimity on issues of tax, a common EU initiative of all member states is lacking. The communiqué of the March ECOFIN meeting 'to further analyse the Commission's proposal, whilst



(From left) The German, Danish and Finnish ministers in discussion prior to a meeting of European Union Ministers of Finance (ECOFIN) in Brussels on 13 March. The ECOFIN meeting failed to reach consensus on an EU-wide financial transaction tax, but member states in favour of the levy can still move forward with their own common initiative.

also exploring possible compromise solutions and alternative routes', therefore seems more like creating an exit option without the EC publicly losing face, than a serious attempt to find a common path to a European tax.

Opposition

The main reason behind opposition to the FTT is of course the wish to protect the profits of the finance industry in the respective countries. But more than that, particularly in the UK, there is a strong and growing opposition to any regulation coming from the EU, because this is seen as a threat to British sovereignty. The Euro crisis has intensified the already existing anti-EU positions, not only among elites but also among a majority of the population. According to sources close to the German finance ministry, the British finance minister George Osborne said they would not even

accept the British stamp duty if it came in the form of European legislation.

No progress in the FTT process is to be expected before June. France will be absorbed by its presidential elections. Germany is – as a result of its strategy in the Euro crisis – suspected of seeking general dominance over the other EU states. This is why Berlin is trying to avoid anything that could further nourish this impression and will strictly follow the formal procedures in Brussels. The June ECOFIN meeting will first have to officially state that no consensus over the EC's proposal or even a compromise version can be reached, before the proponents of the FTT move forward.

In the meantime the proponents might rhetorically move closer to the UK. For instance, German Finance Minister Wolfgang Schäuble has used the term 'stamp duty', but if one

looks closer at what he says, one can see that he includes derivatives and bonds in his version of a stamp duty. The usual Euro-diplomatic blame game is to put the responsibility for failure on the shoulders of others – in this case, and with good reason, on the UK.

Enhanced cooperation

Once the EU-27 approach has been officially declared a failure, the way would be free for a coalition of the willing to advance the FTT initiative. The EU rules allow for such a procedure, called enhanced cooperation. If a minimum of nine member states agree on a common initiative, it can be implemented within the legal framework of the EU. A well-known example is the Schengen Agreement, which regulates migration at the outside borders of the signatory member countries.

Such an agreement on the FTT would take over the core elements of the Commission's draft directive. The nine countries that signed the letter to the Danish presidency would be the appropriate starting point for a coalition. Probably some others would join in the near future, such as Denmark and Slovakia, where the social democrats recently won the elections.

The chances for enhanced cooperation on the FTT are good:

- The European Parliament – although without legislative powers – has several times expressed its support for the FTT and continues to do so in its current debates on the tax.

- The Committee of the Regions, a de facto second chamber representing regional and local authorities, explicitly supports enhanced cooperation if the EU-27 solution should fail.

- There are strong majorities among the populations of most EU countries.

- The FTT can be a source of much-needed revenue to cover the costs of the Euro crisis, in particular as the EU is entering a recession.

- Germany and France have been pushing so hard for the FTT in the last two years that it would be very difficult for them to give up without losing prestige.

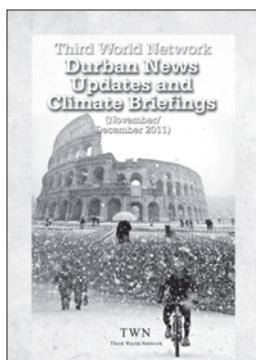
All in all, it might still take some

time, but there is a good chance that the FTT will be realised with the support of a sufficient number of European countries. – IDN-
InDepthNews ◆

Peter Wahl is a researcher at WEED, a German policy institute, where he works on issues of world trade and international finance. This article from the IDN-InDepthNews service is extracted from the EU Financial Reforms Newsletter (March 2012) published by SOMO and WEED.

Durban News Updates and Climate Briefings

(November/December 2011)



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Generics under threat

Can India still supply cheap medicines for the world?

For millions of poor and sick people around the world, the Indian pharmaceutical industry has been something of a life-saver, thanks to its capacity to produce cheap generic versions of expensive patented drugs. However, some recent developments are threatening to undermine India's role as the pharmacy of the developing world. *Martin Khor* explains.

INDIA may be more famous for the Taj Mahal, its religious ceremonies, Bollywood films and one of the highest economic growth rates in recent years. But more than all these, India has had a positive worldwide impact through its large supplies of low-cost, good-quality generic medicines. Millions of lives have been saved or prolonged by this.

Many people go to India to buy life-saving generic medicines from pharmacy shops and bring these back in suitcases to give to close relatives who cannot afford the expensive branded original products.

A decade ago, an Indian company Cipla produced HIV/AIDS generic medicines that could treat a patient for \$300 a year, far cheaper than the branded product's cost of \$10,000 a patient a year. Today, the Indian drug cost has been cut further to below \$80.

This has enabled millions more AIDS patients to be treated. India supplies 70% of the HIV/AIDS medicines obtained by UNICEF, the Global Fund and Clinton Foundation for developing countries.

And 75-80% of medicines (not only for AIDS) distributed by the International Dispensary Association to developing countries come from India. No wonder India has been termed the pharmacy of the developing world.

Obstacles

In January the Indian Drug Manufacturers' Association (IDMA), which has 700 drug companies as members, celebrated its 50th anniversary.



Kenyan AIDS activists and patients march against a planned EU-India free trade agreement that could jeopardise supplies of generic AIDS medicines from India. India has had a positive worldwide impact through its production of low-cost, good-quality generic medicines.

sary. There was much to celebrate, including the industry's high growth, wide range of medicines and its contribution to good affordable drugs.

But there are also many factors that may hinder the continuation of the companies' role as chief supplier of medicines for developing countries.

A main factor of the industry's success has been the Indian government's move in 1970 to exclude pharmaceutical drugs from product patenting. This paved the way for local companies to produce generic versions of the expensive foreign medicines and within a few decades they had taken over 80% of the local market,

while also supplying cheap medicines abroad.

The situation took a negative turn when the intellectual property agreement known as TRIPS was established in 1995 together with the World Trade Organisation. It disallowed countries from excluding medicines from patentability.

However, the TRIPS Agreement allowed countries to determine the criteria for an invention that can be granted a patent, and governments to grant a compulsory licence to local companies to produce the patented products if the latter's requests to patent owners for a voluntary licence do not succeed.

To implement its TRIPS obligations, India passed changes to its patent law in 2005 so that medicines could now be patented. However, the new law also contained the flexibilities such as strict criteria for patentability (trivial changes to a patent-expired product would not qualify for a new patent), allowance for public opposition to a patent application before a decision is made, and compulsory licensing.

India has one of the best patent laws in the world in terms of giving some space to its producers to make generic medicines. But it is also true that the old policy space has been eroded because many new drugs since 2005 have been patented by multinational companies which are selling them at exorbitant prices.

Indian companies can no longer make their own generic versions of these new medicines unless they successfully apply to the government for compulsory licences – which is quite cumbersome – or unless they obtain a licence from the patent-owning multinational, and that usually comes with stringent conditions especially for export.

Another worry is that India is currently negotiating a free trade agreement with the European Union.



A shop in Chittorgarh, India selling generic medicines. India's role as the chief supplier of affordable medicines to developing countries may now be under threat.

Such agreements usually contain provisions, such as data exclusivity and extension of the patent term, which prevent or hinder generic production.

Finally, six Indian companies have recently been bought up by large foreign firms. If this trend continues, the Indian pharmaceutical market may be dominated by multinationals again. It is uncertain whether they will continue to supply the developing world with cheap generic medi-

cines when this may be in conflict with their own branded products.

International health organisations such as UNAIDS, UNITAID and Doctors Without Borders have raised serious concerns that these recent trends may threaten India's role as the chief supplier of affordable medicines to African and other developing countries.

'Millions will die if India cannot produce the new HIV/AIDS medicines in future, it is a matter of life and death,' said Michel Sidibe, UNAIDS executive director, during a visit to India last year.

Thus, a strategy that involves the government and the drug companies is needed to ensure that the local pharmaceutical industry continues to thrive, that it produces not only the existing medicines but also the new medicines even if they are patented, and that they are supplied at affordable prices not only in India but in the rest of the developing world.

That was a sobering message that emerged at the 50th anniversary conference of the Indian drug association, even in the midst of congratulations on the achievements of the past. ♦

Martin Khor is Executive Director of the South Centre, an intergovernmental policy think-tank of developing countries, and former Director of the Third World Network.



A session of the World Trade Organisation's TRIPS Council, the body overseeing implementation of the TRIPS Agreement. By obliging countries to recognise pharmaceutical product patents, the TRIPS Agreement has eroded India's policy space to encourage generics production.

Why generics?

There is much confusion and misconception about the nature and efficacy of generic medicines. The following piece seeks to dispel some common myths and fallacies.

**Jayabalan Thambyappa and
Mohamed Azmi Ahmad
Hassali**

THE cornerstone of access to medicines is affordability, but the stark reality is that life-saving medicines do not always come cheap. It has been reported by the World Health Organisation (WHO) that more than a third of the world's population has no access to essential drugs and more than half of this group of people live in the poorest regions of the developing world such as Africa and Asia. In the case of these two regions, accessibility to drugs is hampered by, amongst other factors, the exorbitant cost of essential medicines. One solution to circumvent this problem lies in the use of generics.



Generic medicines have the same qualities and levels of safety and effectiveness as the originator brands.

What are generics?

Generics are equivalent medicines with the same qualities, safety and effectiveness as the originator brands. Generic medicines contain the same active ingredients in the same pharmaceutical form as the originator product. This simply means that different brands will work in the same way to treat a particular condition, with essentially the same risks and benefits.

Myths and fallacies

A popular misconception is that generics are counterfeit drugs. This arises because generic medicines come in different colours, shapes, packaging and even taste. In addition, the inactive substances (such as lactose, gluten and permitted colourings) in the medicines may differ. These differences do not in any way affect the efficacy of the generic medicines; it must also be emphasised that trademark laws do not allow generic medicines to look exactly like the origina-

tor products. Moreover, originator products as well as generics can be counterfeited.

While on the subject of counterfeit drugs, it is important to note that developed countries have cynically used the legitimate fears of medicines of compromised quality to enhance intellectual property enforcement standards in order to exert greater control over the trade in generic medicines to poor countries. They have negotiated a new treaty, the Anti-Counterfeiting Trade Agreement (ACTA), which, among other measures, requires customs officials to treat generic medicines as if they were counterfeit goods and seize them. (See the article 'ACTA: undemocratic, dangerous and wrong' in this issue.)

In fact, even before ACTA was finalised, on more than 20 occasions between 2008 and 2010, customs authorities in the Netherlands detained consignments of Indian-manufactured generic medicines that were in transit to other developing countries.

Another common misconception

is that generics are inferior to the originator brand in both quality and efficacy. However, quality is assured by good manufacturing practice (GMP) while efficacy is assured by ensuring bioequivalence. It is a false perception that generic medicines are less efficacious than the originator drugs. A generic medicine is bioequivalent to the originator product as it delivers the same amount of active ingredients into the bloodstream of the patient in the same amount of time. In short, bioequivalence ensures that the generic drug is as potent as the originator drug. Thus, quality and efficacy of generics are guaranteed through GMP and also bioequivalence.

Good manufacturing practice and pharmaceuticals

GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimise the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. The main risks are:

- Unexpected contamination of products, which may cause damage to health or even death;
- Incorrect labels on containers, which could mean that patients receive the wrong medicine;
- Insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.

WHO has established detailed guidelines for GMP (http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf#page=106). Many countries have formulated their own requirements for GMP based on

WHO GMP. Others have harmonised their requirements, for example in the Association of South-East Asian Nations (ASEAN), in the European Union and through the Pharmaceutical Inspection Convention.

GMP covers all aspects of production, from the raw materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process, every time a product is made.

As most countries will only allow the import and sale of medicines that have been manufactured according to internationally recognised standards, GMP ensures that products comply with these quality standards.

Bioequivalence

Bioequivalence is defined as 'the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or phar-

maceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study'.

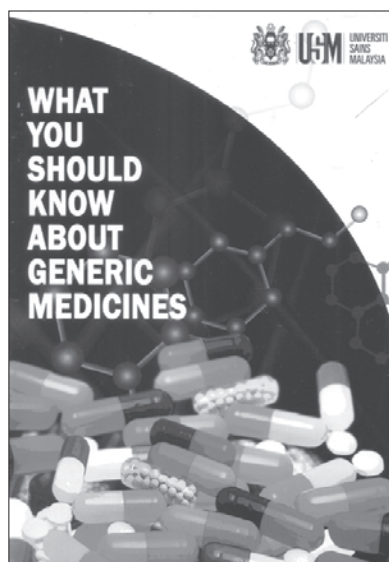
Two medicinal products containing the same active substance are considered bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and their bioavailabilities (rate and extent) after administration in the same molar dose lie within acceptable predefined limits. These limits are set to ensure comparable *in vivo* performance, i.e., similarity in terms of safety and efficacy.

Generic medicine manufacturers are required to prove their formulation exhibits bioequivalence to the innovator product. The purpose of establishing bioequivalence is to demonstrate equivalence in biopharmaceutics quality between the generic product and the innovator product in order to allow bridging of pre-clinical tests and of clinical trials associated with the innovator product. In Malaysia, for instance, the Ministry of Health, through its regulatory body, the Drug Control Authority (DCA), has enforced the need for

bioequivalence to ensure quality, efficacy and safety of the generic pharmaceutical products that are marketed in the country. Most other ASEAN countries too require bioequivalence studies on certain pharmaceutical products. India, which is a leading manufacturer of generic medicines, also adheres to international guidelines that call for bioequivalence of the generics that are marketed.

The US and the European Union have strict guidelines for the manufacture of generics and will not allow the import of these medicines if they do not show proof of bioequivalence and that the countries of manufacture adhere to these international standards. In applications for generic medicinal products in the EU, bioequivalence is fundamental and the approval process for generic drugs is equally as stringent as the process followed to approve branded drugs worldwide. The rigorous chemistry, manufacturing and controls phase is applicable to both new branded drugs and generic drugs. Labelling and testing requirements also are the same for both branded and generic versions. Regulatory authorities evaluate the manufacturing facilities for generics

What You Should Know About Generic Medicines



By Mohamed Azmi Ahmad Hassali,
Jayabalan Thambyappa and Asrul
Akmal Shafie

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16 pp

'The ever-rising cost of medicines has resulted in tremendous pressure on healthcare expenditure for many patients and policymakers around the world. Within this context, the availability of lower-cost generic medicines is seen as a panacea for long-term sustainability of healthcare for both consumers and governments around the world. However, lack of digestible information on generic medicines has unfortunately contributed to low understanding and utilisation among the public. The publication of this book is very timely and commendable as it covers the whole spectrum of information

that a lay person needs to know about generic medicines.'

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and for branded products, using the same standards, to ensure compliance with all good manufacturing practices. The only meaningful difference between the generic and brand approval processes is that human and animal clinical studies to show safety and efficacy are conducted for new branded drugs, whereas bioequivalence studies are used in place of clinical studies in approving generics.

Changing negative perceptions

Providing timely access to affordable, safe and effective medicines should be a priority on every government's health agenda but one stumbling block is prohibitive medicine costs. Not only are they an equally effective alternative in healthcare management, but generic medicines also provide an opportunity for major savings in healthcare expenditure since they may be substantially lower in price than the innovator brands. For instance, it will cost less than \$80 per patient per year to treat AIDS with generics, as opposed to \$15,000 per patient per year if a patented drug were used. According to the then Health Minister of Malaysia, Dr Chua Soi Lek, the monthly cost of treating a patient with HIV in Malaysia in 2004 would be reduced from RM1,200 to approximately RM200 once generic drugs from India were brought in. In fact, Chua went on to say, 'With the cheaper cost, we can treat at least 4,000 HIV patients compared to the present 1,500.' The average cost of treatment per patient was reduced by over 80%, thereby increasing access to medicines to more than twice the number of patients.

WHO has been actively promoting the greater use of generics and even developed countries, through their regulatory bodies such as the US Food and Drug Administration (FDA), have sought to educate consumers on the benefits of using generic medicines. However, on their part, developing-country



A Thai patient receives a dose of generic HIV/AIDS medicines. Generics provide an opportunity for major savings in healthcare expenditure.

governments have not actively involved themselves in educating and convincing consumers on the safety, efficacy and quality of registered generics. This is extremely unfortunate as it is the developing countries that most require access to cheaper and equally efficacious medicines. It is incumbent upon the medicine regulatory bodies in developing countries to

play a bigger role in changing negative perceptions towards generic medicines.

With escalating healthcare costs, governments in many countries have to adopt cost containment measures in an effort to spend their limited financial resources efficiently so that equitable access to healthcare can be provided. In order to achieve optimal outcomes, consumers must not only receive appropriate treatment, but also have the knowledge to use it to its best effect. Governments, healthcare professionals and other relevant agencies have a vital role to play in promoting quality use of medicines through good treatment choices, good communication with consumers, and collaboration with each other. The government has yet another crucial role to play – since generic medicines represent a substantial segment of the pharmaceutical market in many developing countries, the government has to ensure the sustainability of generics production. ♦



World Health Organisation headquarters in Geneva. WHO has been actively promoting the greater use of generic medicines.

Jayabalan Thambyappa, a medical doctor, is Director of the Health and Safety Advisory Centre in Penang, Malaysia. Mohamed Azmi Ahmad Hassali is the head of department for the Discipline of Social and Administrative Pharmacy at the School of Pharmaceutical Sciences at Universiti Sains Malaysia in Penang. They are co-authors, with Asrul Akmal Shafie, of What You Should Know About Generic Medicines (see advertisement on p. 7).

An unhealthy future for the Indian pharmaceutical industry?

In the following analysis of the Indian pharmaceutical industry, *KM Gopakumar* and *MR Santhosh* examine the many challenges facing the industry and the policy options open to the Indian government to avert an impending crisis in its capacity to continue the production of cheap generics.

THE government of India implemented a series of policy measures in the 1970s to achieve self-sufficiency in pharmaceutical production. The first step was to revamp the colonial patent legislation and abandon product patent protection for medicines. Hence, the Patents Act 1970 allowed only process patent protection for pharmaceutical inventions. As a result, Indian companies could produce new medicines which had been introduced in the international market but were not available to needy patients in India. This made possible the production and sale of new medicines at affordable prices.

Secondly, the government introduced control measures on foreign ownership under which foreign companies were not allowed to hold more than 50% of equity.

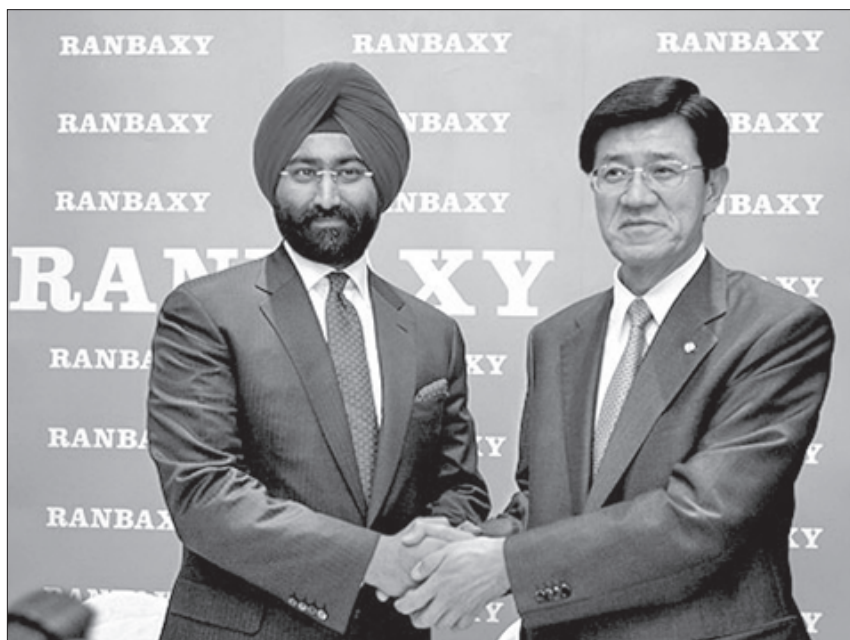
Thirdly, the government introduced direct price control on all formulations of about 347 bulk drugs.

Fourthly, pharmaceutical multinational corporations (MNCs) were forced to start production of both formulation and bulk drugs in India.

Fifthly, public sector production of bulk drugs encouraged the small and medium enterprise (SME) sector to start formulation.

Within a span of some 20 years, these policy initiatives cumulatively made India not only self-sufficient but also a net exporter of generic medicines.

The Indian pharmaceutical industry currently ranks third in terms of volume of production (10% of global share) and is the 14th largest by value (1.5%). Its turnover has grown from a mere \$0.3 billion in 1980 to about \$21.73 billion in 2009-10. The industry consists of more than 5,000 small,



Among recent high-profile acquisitions of Indian pharmaceutical companies by multinational drug corporations was the 2008 takeover of Ranbaxy by Japan's Daiichi Sankyo. Picture shows Ranbaxy MD Malvinder Singh and Daiichi CEO Takashi Shoda after the deal was sealed.

medium and large manufacturers. The domestic market is valued at \$9.44 billion, while pharmaceutical exports in 2009-10 amounted to some \$8.79 billion in value terms.

The Indian pharmaceutical industry plays a critical role in supplying medicines to various global treatment programmes. For instance, Indian generic drugs accounted for approximately 50% of the essential medicines that the United Nations Children's Fund (UNICEF) distributes in developing countries. Besides this, 75-80% of all medicines distributed by the International Dispensary Association (IDA) to developing countries are sourced from India. Similarly, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the US President's Emergency Plan for AIDS Relief (PEPFAR) also source a substan-

tial percentage of their medicine procurement from Indian manufacturers.

While the Indian pharmaceutical industry recorded spectacular growth from 1991 till the first half of the 2000s, it is now facing serious threats to its self-sufficiency and ability to compete in the generic medicines market. Any development that impacts the generic production capabilities in India would compromise access to affordable medicines not only in India itself but also in other countries, developed and developing alike.

There are multiple challenges before the Indian pharmaceutical industry emanating from internal and external sources. The most important challenge is the growing control of the Indian pharmaceutical industry and market by MNCs and their ruthless exploitation and abuse of the product

patent protection afforded by India's current patent regime. How did this situation come about? What were the developments that have contributed to this undermining of the country's self-sufficiency in medicine production and the future availability of generic medicines for its people?

Two policy decisions by the Indian government can be identified as crucial in the emergence of the present crisis facing the industry. The first of these was the change in the government's policy on foreign investment, and the other was the radical change in the country's intellectual property regime to comply with World Trade Organisation (WTO) treaty obligations. Together, both these changes set the country on the present destructive course.

Foreign acquisitions and strategic alliances

In 2001 India liberalised foreign direct investment (FDI) norms for the pharmaceutical sector. As a result, 100% FDI was allowed through the 'automatic route' (without prior permission) in pharmaceutical manufacturing (except in sectors using recombinant DNA technology). The FDI policy did not make any distinctions between 'greenfield' (new facilities) and 'brownfield' (takeover of existing facilities) investments. However, during the last 12 years MNCs did not make any major effort to un-

dertake greenfield investments in India, largely opting for brownfield investments, i.e., acquisition of Indian companies.

In recent years there have been a number of high-profile MNC acquisitions of Indian pharmaceutical companies, starting with the takeover of Matrix Laboratories by US generic manufacturer Mylan Inc in 2006. This was followed by the Japanese corporation Daiichi's acquisition of India's largest pharmaceutical company Ranbaxy. At times MNCs offered purchase prices which were many times higher than the actual sales turnover of the acquired firms. For instance, Abbott paid \$3.7 billion for Piramal Healthcare, whose sales revenue was reported to be approximately \$400 million. Table 1 provides details of several high-profile acquisitions of Indian pharmaceutical companies.

The same period witnessed a series of strategic alliances between MNCs and Indian pharmaceutical companies. Table 2 provides a list of selected strategic alliances. Generally speaking, these strategic alliances take place in any one of the following areas: research and development (R&D), marketing and contract manufacturing. Of the three categories, the dominant form is in the field of contract manufacturing.

MNC acquisitions and strategic alliances should be understood and analysed in the context of changing dynamics in the international pharma-

ceutical market (see below). However, to appreciate the full impact of such foreign takeovers and tie-ups, it is necessary to take into account the far-reaching changes introduced by the Indian government to the country's intellectual property laws.

Product patent protection

In 2005 India reintroduced the product patent regime to comply with the obligations of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This replaced one of the important policy tools used for the development of the Indian pharmaceutical industry. In the absence of product patent protection prior to 2005, the Indian pharmaceutical industry was able to introduce new medicines in the Indian market and abroad within a short period of time at a fraction of the originator's price. Further, competition was generated among Indian pharmaceutical manufacturers because, with no product patents, many companies introduced the same products in the market. This competition, coupled with price control on essential medicines up to the mid-1990s (a 1995 order limited the number of medicines under price control to 74), resulted in the availability of medicines at low prices.

The reintroduction of product patentability takes away the freedom of Indian pharmaceutical companies

Table 1. Select Cases of MNC Acquisitions in the Indian Pharmaceutical Sector

Target company	Acquirer	Country of origin	Year	Amount
Matrix Laboratories	Mylan Inc	US	August 2006	\$736 mn
Dabur Pharma	Fresenius Kabi	Singapore	20 April 2008	\$219 mn
Ranbaxy Laboratories	Daiichi Sankyo	Japan	11 June 2008	\$4.6 bn
Shantha Biotech	Sanofi Aventis	France	27 July 2009	\$783 mn
Orchid Chemicals (injectable business)	Hospira	US	16 December 2009	\$400 mn
Piramal Healthcare (domestic formulation)	Abbott Laboratories	US	21 May 2010	\$3.72 bn
Paras Pharmaceuticals	Reckitt Benckiser Group	UK	14 December 2010	\$720.6 mn

to introduce generic versions of new chemical entities (NCEs) in the normal course because NCEs often come with product patent protection. Thus, a company like Cipla, for example, can no longer see a repeat of its historic announcement in 2000 of making available generic first-line HIV/AIDS medicines for just \$350 per person per year against MNC prices of \$10,000-12,000. Under the product patent regime, a generic version of a patented NCE can be introduced in the market only by having recourse to flexibilities in the patent law, viz., patent opposition, compulsory licensing or parallel importation.

Seven years after the introduction of product patent protection, there is ample evidence of growing control of

MNCs in the Indian pharmaceutical market. Figures released by the Indian Patent Office reveal that out of 3,488 product patents issued from 2005 to March 2010, 3,079 were granted to MNCs.

Further, an unpublished study by one of the authors has found that, out of 413 NCEs approved by the US Food and Drug Administration (FDA) in 1995-2010, only 240 obtained a marketing licence from the Indian drug regulatory agency. Out of these 240 NCEs registered for marketing approval in India, only 160 are available from generic manufacturers. This shows that there is no generic availability for some 80 NCEs. Moreover, more than 170 NCEs are not even available in India.

Even if these 170 non-available NCEs and the 80 NCEs without generic versions may not be important from a public health perspective, it is a clear indication of the growing gap in the availability of new medicines. This is also evident from the fact that out of the 108 NCEs approved by the FDA for marketing in 2005-10, only 52 are available in India. The drying up of the generic pipeline is further illustrated by the fact that out of the 52 NCEs, generic versions are available for only 14.

A recent study by Prof. Sudip Chaudhuri from the Indian Institute of Management provides ample evidence of the growing control of MNCs in the Indian pharmaceutical sector. According to the study, from

Table 2. Select Cases of Strategic Alliances between Indian Companies and Foreign Partners

Partnering firm in the Indian pharmaceutical sector	Foreign partner	Description of alliance	Nature of alliance
GVK Bio Sciences	INC Research	Joint venture will establish a dedicated resource capability to offer phase I-IV clinical development programme in India	R&D alliance
Advinus Therapeutics	Merck	Discovery and clinical development collaboration on metabolic disorders	R&D alliance
Pall Pharamlab Filtration	Euroflow Ltd, UK	Distribution of Euroflow's chromatography products and technologies in India	Sales and distribution
Ranbaxy Laboratories	Blansett Pharmacal Co., US	Sales support to Ranbaxy's DisperMox (amoxicillin tablets for oral suspension) in the US	Sales and distribution
Wockhardt	Ranbaxy Pharmaceuticals Inc., US	Marketing of Wockhardt's bethanecol chloride tablets in the US	Market development, sales and distribution
Orchid Chemicals and Pharmaceuticals	Apotex Corp, US	Sale of Orchid's generic cephalosporin and other injectable products in the US	Market development, sales and distribution
Nicholas Piramal	BioSyntech, Canada	Drug research and development in biotechnology. The collaboration centres on the drug BST-Inpod which is being developed to alleviate chronic heel pain.	R&D alliance
Ranbaxy Laboratories	GlaxoSmithKline, UK	Development of new chemical entities or new drugs in the areas of urology, anti-fungal, anti-bacterial and metabolic disorders	R&D alliance
Dabur India	Abbott Laboratories, US	Marketing of a number of Dabur products in the US on an exclusive long-term basis	Market development, sales and distribution
Ranbaxy Fine Chemicals	Mallinckrodt Baker Inc (MBI), US	Ranbaxy Fine Chemicals will market MBI's range of scientific laboratory products in the Indian market	Market development, sales and distribution
Wockhardt	Eisai Company Ltd, Japan	Wockhardt will market Methycobal in India	Market development, sales and distribution
Nicholas Piramal	Biogen Ideac, US	Nicholas Piramal will market Avonex for multiple sclerosis in India	Market development, sales and distribution

Source: Santhosh (2011)

1995 to 2010, there were 180 NCEs and new biological entities (NBEs) in India in terms of value. Of these 180 new medicines, MNCs are marketing 92 in India and enjoy a monopoly over 34 medicines. [The monopoly status is based on the actual monopoly in the market (single source producer) and not on the patent status in India.] These 34 medicines, which account for 31% of their sales of the 92 medicines, fall into the following therapeutic areas: anti-cancer (11); cardiac (7); anti-infectives (5); analgesics (3); neurological (4); anti-diabetic (3); and ophthalmological (1). The study lists the exorbitant prices charged for the 34 monopoly medicines.

The study also reveals a growing trend of importation of patented medicines by MNCs. Even though there is an export surplus, 'importation has grown at a faster rate than exports, leading to a decrease in formulations trade surplus' (Chaudhuri, 2011). The value of formulation imports expanded from \$69.5 million to \$1,096.1 million between 1995 and 2010, at a compound annual rate of growth (CARG) of 20%. During the same period, exports grew at 17% CARG.

Against this background, Prof. Chaudhuri considers direct price control of patented medicines. According to him, 'Price control is not forbidden under TRIPS or any other agreement of the WTO. The Draft National Pharmaceuticals Policy, 2006 (p. 15) recommended mandatory price negotiations of patented drugs before granting marketing approval and stressed the importance of studying the experiences of Canada, Australia, France and other countries believed to have a good system.'

Comparing price control with compulsory licensing, Chaudhuri says that price control, 'if properly implemented makes drugs more affordable but does not provide any room for the generic companies. [Compulsory licensing] not only makes the prices more affordable through competition. It also ensures some space to the generic companies, which is vital for their long term sustenance'.

A study by Dinesh Abrol et al. (2011) examining the post-TRIPS be-

haviour of MNCs in India states, 'Strong IPRs [intellectual property rights] have not favoured India with the claimed benefits of increased access to good quality FDI, technology transfer, overseas product R&D and stimulation of domestic investment in R&D for product innovation for local needs.' On the technology transfer front, the study says, 'During the pre-TRIPS era foreign pharmaceutical firms often exhibited in India an almost near complete aversion to technology transfer in bulk drug production. Evidence collated on the recent patterns of technology transfer from foreign firms to domestic companies shows that the results are not very encouraging for pharmaceuticals.' Regarding investment in R&D for drug development, the study finds that Hoechst and Astra, which carry out limited drug discovery operations in India, still remain, 'while others have closed down the units that had the mandate to develop products for the benefit of local markets'.

These studies in fact provide further basis to support the argument for using flexibilities allowed by the TRIPS Agreement to introduce generic versions of patented medicines. In this regard, the Indian Patents Act's provisions on compulsory licensing provide an effective tool to curb the abuse of patent monopoly.

Recently the Indian Patent Office issued domestic drug company Natco Pharma with a compulsory licence (CL) to produce pharmaceutical MNC Bayer's anti-cancer medicine sorafenib tosylate. As a result of the CL, the medicine would be available to patients in India for Rs8,800 per month, against Bayer's price of Rs280,000 per month. (See the article 'The compulsory licence on

sorafenib: A right step to ensure access to medicines' in this issue.)

This decision of the Patent Office is expected to generate more applications for CLs in the coming days. There are many medicines under product patent protection in India which are prohibitively priced. These medicines are ideal candidates for CLs.

However, currently there are no pending CL applications before the Patent Office. Indian companies are believed to be adopting a wait-and-see stance by keeping track of the developments with regard to the sorafenib CL. Further, there is a need to finetune both procedural and substantive legal provisions on compulsory licensing, especially the time period for the disposal of CL applications, royalties and conditions for granting CLs.

However, the most important threat against the use of CLs in future comes from MNC acquisitions of Indian pharmaceutical companies and strategic alliances. These have the potential to eliminate the possibilities of using flexibilities in the Indian Patents Act to ensure access to medicines. The dominance of MNCs over the Indian pharmaceutical market resulting from acquisitions and strategic alliances would neutralise the use of flexibilities like compulsory licensing.

Acquisitions, alliances and adverse effects on access to medicines

The global pharmaceutical industry is undergoing unprecedented levels of transformation. The 'blockbuster drugs model' followed by the pharmaceutical MNCs is now under

Table 3. MNCs and Generic Subsidiaries

MNC	Generic subsidiary
Novartis	Sandoz
Pfizer	Greenstone Ltd
Merck	BioVentures
Daiichi	Ranbaxy
Abbott	Nicholas Piramal

severe crisis. The R&D pipeline has dried up to a great extent and the number of NCEs has come down significantly. Moreover, the MNCs are also expected to be hit by the expiry of patents on existing molecules. In fact, almost all the blockbuster drugs of pharmaceutical MNCs are going to be off-patent in the near future. In addition, Indian generic companies started challenging the patents on blockbusters. As a result, the global generic market, especially in the regulated market, is growing rapidly.

Another important problem facing the industry is that, with the global financial crisis, the developed countries have begun cutting social security spending as part of their economic austerity measures. This is expected to have implications for out-of-pocket drug expenditures as well as public procurement of drugs.

In order to meet these challenges, MNCs have resorted to various strategies, one of which is to control the generic medicine market. Acquisitions of and strategic alliances with generic companies should be understood in this context. The following are among the strategies adopted by the MNCs to face the ongoing crisis in their business model:

- Set up standalone generic companies to cash in on the growing generic market (see Table 3). This is a clear departure from the earlier business model, with MNCs now focusing on both patented and off-patent medicines. This would enable MNCs to gain dominance over the generic market and control the introduction of generics.

- Get into strategic alliances and contract manufacturing deals with generic players from the developing countries in order to source products in a cost-effective manner. This would deter the generic companies from entering into R&D activities which would result in the development and marketing of new drugs or the aggressive introduction of generic versions of patented drugs.

- Establish stronger intellectual property regimes to ensure and extend monopoly in the market. This is sought to be achieved through

‘TRIPS-plus’ measures (which go beyond the standards set by the TRIPS Agreement) imposed by free trade agreements (like the Trans-Pacific Partnership Agreement) and stricter intellectual property enforcement standards (through initiatives like the Anti-Counterfeiting Trade Agreement).

- Enter into emerging markets through acquisitions and strategic alliances.

As indicated above, such acquisitions and alliances have far-reaching consequences and can potentially compromise access to affordable medicines. Judging from previous takeovers, it is evident that the MNCs are mainly targeting Indian companies with a high level of technological capability. If the takeover drive is left unchecked, India would suffer severely especially in the realm of innovation. Since Indian companies would get locked into the lower end of the value chain, India would be forced to compromise on need-based R&D and become completely dependent on MNCs for meeting the country’s drug needs in the long run.

Secondly, such acquisitions would neutralise the flexibilities permitted under the TRIPS Agreement. The presence of an active domestic sector with technological capabilities is needed to make use of the TRIPS flexibilities such as compulsory licensing and patent opposition. MNC acquisitions of domestic generic companies would either fully eliminate or restrict the use of flexibilities. For instance, immediately after its takeover by Daiichi, Ranbaxy withdrew all the patent challenges against Pfizer’s blockbuster cholesterol drug Lipitor.

Thirdly, these acquisitions would result in the capture of the marketing and distribution networks of Indian generic companies. Takeovers are an easy way to establish a marketing and distribution system in a country and substitute low-cost medicines with higher-priced, including patented, versions. For example, the main objective of Abbott’s acquisition of Piramal Healthcare was to acquire the latter’s marketing and distribution network, as Abbott acquired only one

manufacturing facility from the Piramal group. With this takeover, Abbott now ranks first in market share in India. (Abbott has also made it clear that there is no plan to start exporting from India.)

Fourthly, the MNCs are seeking to buy and kill off the competition in a global generic market which is growing at a fast pace. MNCs want to restrict the Indian companies from getting into the regulated markets with their low-priced generic products. At the same time, the MNCs are also devising their strategies to capture the Indian market, which, while relatively small in global terms, is one of the fastest-growing pharmaceutical markets.

Fifthly, these acquisitions would result in high medicine prices. According to the Indian Pharmaceutical Alliance, an association of Indian pharmaceutical companies with R&D activities, Abbott increased the prices of medicines produced by Piramal immediately after its takeover. For example, the price of Haemaccel was Rs99.02 in May 2009; by May 2011 it had gone up to Rs215 – a 117% increase in the space of two years. In another instance, the epilepsy drug Gardenal registered a price hike of 121% during the same period.

The issues relating to takeovers and high drug prices have triggered considerable debate and discussion among policymakers and commentators in India. Some of the concerns discussed above were shared by the parliamentary standing committee on health, which in a July 2010 report referring to the acquisition of Indian pharmaceutical companies stated: ‘These developments would result in MNCs gaining market supremacy and essential medicines are bound to become costlier. The Committee would appreciate if the Ministry of Health and Family Welfare takes up this issue with the Ministry of Chemicals and Fertilisers without any delay to come up with policy options to ensure that major Indian pharma companies remain in Indian hands.’ Likewise, the Ministry of Health and Ministry of Commerce and Industry opposed such acquisitions.

A High-Level Expert Group Report on Universal Health Coverage for India released in October unambiguously stated that 'we also need to urgently revisit India's FDI regulations to amend the present rules of an automatic route of 100% share of foreign players in the Indian industry to less than 49%, so as to retain predominance of Indian pharmaceutical companies and preserve our self-sufficiency in drug production'. Similar concerns were also expressed by many public interest organisations such as the All India Drug Action Network, the Centre for Trade and Development (Centad) and the Delhi Science Forum. The parliamentary standing committee on commerce is currently examining the issue in detail.

Responding to these concerns, a high-level meeting chaired by the Prime Minister in October adopted, with a slight modification, the recommendations of the Arun Maira Committee which had been appointed to consider a policy response to the issue of FDI in the Indian pharmaceutical sector. The decision amends the existing policy which allows 100% FDI in the sector under the automatic route, and differentiates between greenfield and brownfield investments. Further, brownfield investments will be routed through the Foreign Investment Promotion Board as a transitional arrangement for six months. The Competition Commission of India (CCI), which regulates mergers and acquisitions, has also been charged with overseeing such investments. A six-month transition period is also provided to amend the Competition Act and Rules to equip the CCI with the powers to effectively perform the function. This shows that the government has decided to use only competition law to address the concerns emerging out of acquisitions of Indian generic companies by the MNCs.

The power of the CCI to inquire into mergers and acquisitions is already enshrined in Section 20 of the Competition Act. Sub-section (4) of Section 20 states: 'For the purposes of determining whether a combination

[mergers and acquisitions] would have the effect of or is likely to have an appreciable adverse effect on competition in the relevant market, the Commission shall have due regard to all or any of the following factors'; it goes on to list 14 factors. Hence, the focus of the Commission is to approach the issue from a competition point of view. The Competition Act and the Commission are not equipped to deal with the abovementioned issues which are completely out of the purview of the competition law but which are crucial to access to medicines. Another important shortcoming of the competition law approach is that the decisions of the Commission would be subjected to judicial review and may be overturned by the courts.

Therefore it is important for the government to put in place a policy-oriented approach and the appropriate tools to address the policy concerns stemming from the acquisitions of Indian pharmaceutical companies.

Conclusion

Any development that affects the Indian pharmaceutical industry would impact on developing countries' access to medicines. The introduction of a product patent regime took away the freedom that had previously been available for Indian pharmaceutical companies to introduce generic medicines. Generic versions of patented medicines can now only be produced by invoking the TRIPS flexibilities which have been incorporated in the Indian Patents Act.

However, only a few Indian pharmaceutical companies are making use of these flexibilities to introduce generic versions of NCEs. The legal provisions should be finetuned to simplify recourse to these flexibilities. Further, the government has to encourage the use of these flexibilities through policy tools and capacity enhancement.

Importantly, there is a need to address MNCs' growing control over the Indian pharmaceutical market, which poses a major threat to the use of TRIPS flexibilities and can under-

mine access to medicines. The Indian government's policy response to this threat so far has fallen well short of what is required, especially in dealing with acquisitions and strategic alliances. The need of the hour is to develop multi-level policy responses to curb direct and indirect acquisitions of domestic generic companies with the objective of creating an enabling environment for the generic industry to stay in business and move up the value chain. In doing so, access to affordable medicines must be safeguarded at all times. ♦

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The EU-India free trade agreement and access to medicines

The free trade agreement which India is negotiating with the European Union threatens to jettison some of the health safeguards in India's patent legislation which make possible the production of cheap generic medicines. *Kajal Bhardwaj* identifies the draft treaty provisions which raise serious concern.

SINCE 2007, India and the European Union (EU) have been negotiating a free trade agreement (FTA) that has attracted global concern over its potential impact on the manufacture, supply and distribution of generic medicines from India.

Till recently, the EU had not figured among the developed nations that aggressively pursue intellectual property protection in excess of the World Trade Organisation (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These so-called TRIPS-plus provisions, which are known to have an adverse impact on generic production, typically featured in FTAs negotiated by the United States such as the North American Free Trade Agreement (NAFTA), the Central American Free Trade Agreement (CAFTA) and a host of other US FTAs negotiated with developing countries.

However, leaked versions of the EU-India FTA negotiation texts in 2009, 2010 and 2011 show that the EU, in a stark departure from its traditional model of trade negotiations, is now demanding ambitious TRIPS-plus measures of developing countries (Bilaterals.org). In the case of India, the demands, if accepted, would have an impact not just on patients in India but also on those across the developing world.

Patents and access to medicines in India

Between 1975 and 2005, India built up its capacity to produce safe, effective and affordable generic medicines. The country's 1970s patent law played an important role in the development of the Indian generic indus-

try as it did not allow 'product patents' on pharmaceuticals and enabled Indian companies to make their own generic versions of medicines.

The clearest impact of India's generic production has been in the case of antiretrovirals (ARVs) for the treatment of HIV/AIDS. Competition from and between Indian generic producers has resulted in reductions in the prices of first-line AIDS medicines from as much as \$15,000 to as little as \$60 per person per year (Medecins Sans Frontieres, 2011). In addition, the lack of product patents on each separate drug allowed Indian generic manufacturers to combine three different AIDS medicines in one single pill. The availability of these generic fixed-dose combinations has dramatically simplified AIDS treatment in resource-limited settings and has resulted in government treatment programmes across the developing world. Over 6.6 million people living with HIV are now on treatment in developing countries, the majority on Indian-made generic ARVs. A 2010 study which examined the purchase of donor-funded HIV medicines found that, 'among paediatric ARV and adult nucleoside and non-nucleoside reverse transcriptase inhibitor markets, Indian-produced generics accounted for 91% and 89% of 2008 global purchase volumes, respectively' (Waning et al., 2010).

Changing scenario: India starts granting patents on medicines

In 2005 India had to amend its patent law to become compliant with its obligations under the WTO's TRIPS Agreement. As opposed to its

1970s patent regime, TRIPS required India to start granting 20-year product patents on medicines. Product patents give patent holders exclusive rights over the manufacture, sale, use, offer for sale and import of the patented medicine. This allows them to exclude competitors or generic companies from producing the medicine and the lack of competition results in high prices and restricted availability.

While debating the impact of complying with these requirements of the TRIPS Agreement, the Indian Parliament recognised that the WTO rules could pose a significant barrier to generic production and access to medicines. They turned to the 2001 Doha Declaration on the TRIPS Agreement and Public Health signed by all WTO members that states categorically that TRIPS 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all' (World Trade Organisation, 2001).

The Indian Parliament thus included multiple health safeguards in the amendments to India's patent law, including a provision restricting 'evergreening', i.e. the practice of pharmaceutical companies extending their exclusive rights on a medicine by making minor or obvious changes to the medicine and applying for additional patents. Section 3(d) of India's patent law accordingly prohibits its patents on new forms of existing medicines unless the patent applicant can show a significant increase in efficacy. The law also allows health groups to challenge patent applications, and people living with HIV, cancer and hepatitis C have used these

provisions to ensure that frivolous patents are not granted on key medicines in India (Chaudhuri et al., 2010).

Beyond TRIPS: The EU-India FTA negotiations

Several of the health safeguards included by the Indian Parliament in the Indian patent law are now at risk of being overturned or undermined by the TRIPS-plus demands of the European Commission – the executive arm which negotiates on behalf of the EU – in the EU-India FTA negotiations. There are three distinct areas of concern in the ongoing negotiations that could adversely impact India's generic production capacity and, consequently, the ability of patients in India and across the developing world to access safe, effective and affordable generic medicines from India. These are the *intellectual property chapter*, the *investment chapter* and the *regulatory standards chapter*.

Although the regulatory standards chapter is not discussed for the purposes of this article, demands that India harmonise its drug regulatory standards with those of the EU have caused concern regarding the ability of Indian generic companies to meet such standards and whether these standards could also become a barrier to generic production. More vocal critics of the attempts by developed countries and the multinational pharmaceutical industry to promote the upward harmonisation of regulatory standards have pointed out that such standards are designed only to be met by well-resourced companies and would ultimately squeeze generic companies out of production (*Essential Drugs Monitor*, 2001).

The intellectual property (IP) chapter

The IP chapter that is being negotiated between the EU and India is comprehensive and covers a broad range of IP issues including copyright, geographical indications and patents (including as they impact agro-chemicals and seeds). However, this article focuses on the demands by the EU in

the IP chapter as they relate to access to medicines. Among the primary demands of the EU in this regard are:

Patent term extension: Since 2005, when India changed its patent law to comply with the TRIPS Agreement, it has been granting 20-year patents on products and processes as required by TRIPS. Also known as 'supplementary protection certificates', patent term extensions would require India to extend the patent term beyond 20 years if there is any delay in the granting of a patent or in obtaining marketing approval for the medicine.

A longer patent term would mean that the monopoly period enjoyed by the patent holder would get extended and delay the entry of generic medicines. A study by the Korean National Health Insurance Corporation on similar demands for patent term extension by the US in the context of the South Korea-US FTA negotiations concluded that the extension of patent term could cost the Corporation \$529 million for extending drug patents for three years and \$757 million for a four-year extension. In addition, critics argue that such a mechanism can place undue pressure on the patent office to grant a patent or on the drug regulator's office to grant marketing approval without due consideration.

Data exclusivity: Generic manufacturers, when seeking marketing approval for their products, do not have to conduct clinical trials on medicines already introduced in the market. Duplicate clinical trials on human populations for a medicine whose safety and efficacy is already proven are considered unethical. They would also add considerably to the cost of generic production. Instead, under the regulatory laws of most developing countries, generic manufacturers have to show that their generic versions are 'bioequivalent' to the medicine already approved and on the market.

Data exclusivity as demanded by the EU in the FTA negotiations would require generic manufacturers to conduct their own clinical trials to get marketing approval or wait till a specified exclusivity period is over (five

to 11 years) before a generic product is approved. This measure creates exclusivity over medicines separate from patents and applies even to medicines that are off-patent or where a compulsory licence is issued. In Guatemala, price differences in the same therapeutic class of medicines range up to 845,000% because of data exclusivity (Shaffer and Brenner, 2009). In Jordan, a 2007 study by Oxfam showed that of the 103 medicines registered and launched since 2001 that had no patent protection in Jordan, at least 79% had no competition from a generic equivalent as a consequence of data exclusivity (Oxfam, 2007). Both Jordan and Guatemala impose data exclusivity as a result of their FTAs with the US.

Enforcement measures: A key area that the leaks of the IP negotiation chapter have highlighted is the EU's interest in aggressive IP enforcement, widely considered the latest front in the IP battle between the North and the South. Best reflected in the secretly negotiated Anti-Counterfeiting Trade Agreement (ACTA), IP enforcement entails measures that significantly alter how IP holders like multinational pharmaceutical companies can use public resources, money and authorities to enforce their private rights. The impact of such aggressive IP enforcement measures has been seen in 2008 and 2009 when generic medicines on their way from India to Africa and Latin America were seized at European ports (Health Action International et al., 2009). Under the EU Customs Regulations, customs officials did not require proof of patent infringement or even that the generic medicines would enter the European market before they took these actions.

Several of the provisions of ACTA feature in the EU-India FTA negotiations. Among these are provisions that increase the ability of patent holders to get court orders stopping generic medicines from reaching the market before even having proven that their patents are being infringed. Indian courts have held that in the case of medicines, courts would be extremely careful before granting such 'injunctions'. However, the EU's

demands would broaden the circumstances in which patent holders can ask courts for such orders and upset the fine balance the Indian courts are seeking to establish between patent rights and public interest. In addition, the EU is also seeking what is known as ‘third party liability’, which would allow patent holders to involve the entire manufacture, supply and distribution chain in patent disputes. This could include API (active pharmaceutical ingredient) manufacturers, truckers, pharmacies and even NGOs that are treatment providers. TRIPS-plus IP enforcement measures are thus likely to have a chilling effect on generic production and supply.

The investment chapter

In 2011, the European Commission received a mandate from the European Council to include an ‘investment’ chapter in the EU-India FTA negotiations. The investment chapter would contain provisions designed to protect the interests of European investors in India and would be similar to provisions contained in bilateral investment treaties or BITs. In recent years, more and more examples of how investment provisions are used by investors to prevent governments from adopting pro-public-interest regulations related to health, environment, development, etc. have come to light.

The investment chapter can impact access to medicines and the use of TRIPS flexibilities by India in several ways. Investment rules typically define investment to include intellectual property rights and prohibit the ‘expropriation’ of such investments by the government or require ‘fair and equitable treatment’ for EU investors. These terms are not defined anywhere and companies use these provisions to challenge pro-health or pro-environment laws and policies. In addition, where a company alleges such expropriation, it can sue the Indian government in secret, private international arbitration instead of local courts. The clearest examples are the cases filed by tobacco company Philip Morris against Uruguay and, more

recently, Australia. Philip Morris is alleging that tobacco warnings on cigarettes or rules for plain packaging amount to infringements of its trademarks, which are considered to be ‘investments’. The investment provisions have also been used to challenge, for instance, Poland’s attempts to regulate its health insurance industry or the ability of Canada to regulate chemicals that can cause health problems.

Experience has shown that, regardless of the soundness of these legal actions, the fact that they are in private international arbitration, the exorbitant compensation awarded to investors and the high legal costs for defending such cases have had a chilling effect on government regulations. Moreover, these private arbitration panels do not take human rights or Constitutional obligations of governments into account in making their decisions and are increasingly under scrutiny for reflecting institutional biases within the international investment regime (Van Harten, 2010).

In addition, unlike existing bilateral investment treaties between some European countries and India, the investment chapter in the FTA would also contain so-called ‘market access’ or ‘performance requirements’ that essentially prevent governments from imposing conditions or restrictions on foreign investors. In the case of companies producing essential products like medicines, this is a cause for concern. The market access provisions would make it extremely difficult for the Indian government to ensure, for instance, that pharmaceutical companies continue to produce key essential medicines or to impose safeguards in the takeover of Indian pharmaceutical companies by multinational companies.

State of play

In April 2011, the Indian Prime Minister’s Office issued a press release stating that nothing in the EU-India FTA would go beyond TRIPS or India’s domestic law (Prime Minister’s Office, 2011). Sources indicate that the European Commission has

now shifted negotiation tactics to argue that several of its demands are within the TRIPS framework or are already present in Indian law. For instance, the EC’s position on whether data exclusivity is required by the TRIPS Agreement has been vague and any attempt to replicate the provisions of the TRIPS Agreement in the EU-India FTA may be used by the EC at a later stage to argue that TRIPS requires data exclusivity. Under the WTO framework, the EU would have to take the Indian government to the WTO’s dispute settlement body to settle this issue in a public dispute. But under the FTA, these discussions would be subject to secret arbitration between the EU and India. In addition, the EC also appears to be arguing that the IP enforcement measures it is demanding are within the scope of the Indian law.

In February 2012, the 11th EU-India Summit was held in New Delhi. One of the key areas identified by the EC to be discussed at the Summit was to speed up negotiations on the FTA. According to news reports from the Summit, it appears that both India and the EC stuck to their stands on various contentious issues in the FTA (Alexander, 2012). Although the European side announced after the Summit that the FTA would be ready for signing by the end of 2012, similar public enthusiasm for a quick resolution of the FTA on the Indian side is noticeably lacking.

Among the specific TRIPS-plus demands of the EC that are of concern, the EC claims that it is no longer demanding patent term extension or EU-style data exclusivity. However, as the negotiation texts continue to be secret, it is difficult to ascertain the actual shift in the position of the EC. Also, as noted above, even if the EC drops its demand for EU-style data exclusivity, it may still argue that data exclusivity of some sort is required by the TRIPS Agreement.

A bilateral agreement, a global movement

The negotiations between India and the European Union have sparked

global protests. With most developing countries dependent on India for their supply of medicines, the impact of the EU's demands will be felt across the South. In addition, several other developing countries are also negotiating FTAs with the EU and the FTA with India is widely considered to be the template for these negotiations. For several developing countries, India's ability to resist the EU's TRIPS-plus demands would create an important precedent. Protests against the EU-India FTA have taken place across the globe. The most recent round of protests was held around the EU-India Summit and demonstrations were held in Nepal, the UK, Kenya, South Africa and Malaysia (Delhi Network of Positive People, 2011). Concern over the impact of the EU-India FTA has also been expressed by the Joint United Nations Programme on HIV/AIDS (UNAIDS), the UN Development Programme (UNDP), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the UN Special Rapporteur on the Right to Health.

A free trade agreement is a binding legal instrument and the Indian Parliament would have to amend India's laws while the government would have to make changes in policies to implement this trade agreement domestically. A change in India's patent laws that prioritises the interests of the multinational pharmaceutical industry over the right to health and access to medicines will impact millions in India and across the developing world who rely on Indian generic medicines to treat not just HIV, but also cancer, heart disease, blood pressure, mental illness, etc.

What the European Commission is demanding of the Indian government jeopardises the hard-fought-for balance between public interest and intellectual property rights that the Indian Parliament sought in 2005. The patent system is already having an impact on the availability of generic medicines from India. Patented hepatitis C medicines, for example, which are also required by people living with HIV who are co-infected with hepatitis C, cost anywhere between \$7,000 and \$10,000 for a treatment course

(the treatment cost varies with the relationship between the doctor and pharmaceutical company). The TRIPS-plus demands of the EC threaten to make a bad situation worse.

Even as global public opinion and the activism of people living with HIV across the developing world appear to have forced some manner of retreat by the European Commission on its most aggressive demands, the Indian government must continue to remain vigilant and resist all EU demands that may have an adverse impact on access to medicines. This also applies to other FTA negotiations as well as other methods being used by the multinational pharmaceutical industry and developed countries to introduce TRIPS-plus measures in India, including through litigation, lobbying and the training of law and policy makers and judges.

A change in India's patent laws that prioritises the interests of the multinational pharmaceutical industry over the right to health and access to medicines will impact millions in India and across the developing world.

Equally important is the resistance of other developing countries to similar TRIPS-plus demands in FTAs they are negotiating with developed countries. If India resists the EU's demands but importing countries impose TRIPS-plus provisions, their ability to access Indian generics or even produce their own would be severely restricted. The EU-India FTA negotiations are taking place at a time when the US has also restarted its FTA project with an ambitious Trans-Pacific Partnership Agreement (TPPA) aimed at covering several developing countries in Asia and Latin America.

While the EU, the US and even

Japan appear to have a co-ordinated strategy promoting TRIPS-plus measures in the name of trade that will adversely impact generic competition, developing countries appear unable or unwilling to create a common platform for resisting these efforts. As more and more developing countries grapple with the adverse impact of the TRIPS Agreement and the calls for its review get louder, the frenzied pace at which FTAs with TRIPS-plus measures are being negotiated contradicts the increasing evidence that heightened intellectual property protection risks the lives and health of millions across the South.

Since the imposition of TRIPS on developing countries, public interest and health groups and communities of people living with HIV, cancer and other diseases have taken the lead, through the use of legal measures or activism, to ensure that trade rules do not hamper access to medicines. As developing countries struggle with shrinking budgets and expanding universal access to healthcare, it is time that these governments band together behind the vision best expressed by Indian Prime Minister Indira Gandhi at the 1981 World Health Assembly which adopted the Global Strategy of Health for All – that the idea of a better ordered world is one where medical discoveries are free of patents and there is no more profiteering from life and death. ♦

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The IMPACT Counterfeit Taskforce, Intellectual Property Rights Enforcement and Seizure of Medicines

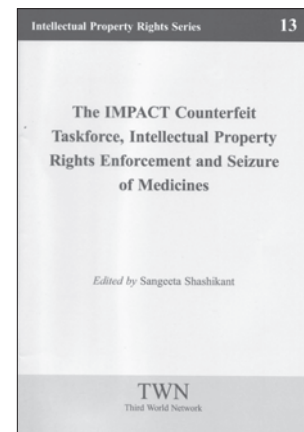
Edited by Sangeeta Shashikant

There has in recent years been a major push to set restrictively high standards of intellectual property (IP) protection and enforcement internationally. Driven by large corporations and governments of industrial countries, this push extends even to the critical medicines and medical products sector.

In this sector, the introduction of stricter IP enforcement measures is sought, among others, through pursuing the agenda of combating "counterfeits". This book looks at recent moves at the World Health Organisation (WHO) to seek endorsement of an initiative called the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and its proposed definition of counterfeits. This approach has drawn criticism from many developing-country WHO members for seeking to address health issues relating to the quality and safety of medical products through an IP framework.

Concerns over the focus on counterfeits have been heightened by a spate of seizures by European customs authorities of generic medicines in transit to developing countries on grounds of IP infringement. These seizures have further fuelled fears that linking health and IP issues would impede production of and trade in affordable, good-quality generic drugs – and poor countries' access to them.

This book is a compilation of articles – most of which appeared in the *South-North Development*



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Monitor (SUNS), a daily bulletin on development issues published by the Third World Network – which examine the concerns expressed by developing countries and civil society over the anti-counterfeit drive and medicine seizures, and report on the lively recent debates on these subjects at WHO and the World Trade Organisation (WTO).

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‘Protect our medicines, our health, our lives’

The EU-India Summit in February touched off protests by health activists and civil society groups both in India and around the world against the free trade agreement currently being negotiated between these parties. *Ranja Sengupta* reports.

OVER 1,500 protesters took to the Delhi streets on 10 February, crying ‘Europe, hands off our medicine’ as they voiced their opposition to the Bilateral Trade and Investment Agreement (BTIA) that is currently being negotiated between the European Union and India.

The BTIA, or free trade agreement (FTA) in common usage, has been under negotiation since 2007; while voices of analysts, activists and people whose lives will be directly affected have risen in protest, the determination on both sides to reach ‘an ambitious agreement’ continues unabated. The EU-India Summit, held on 10 February, was to see the culmination of these ambitions, activists feared.

Protesters carried a giant medicine pill through the streets of Central New Delhi, the powerful visual imagery highlighting India’s role as the ‘pharmacy of the developing world’ which faces a severe challenge from the EU’s demands to include harmful intellectual property (IP) provisions in the FTA. ‘No pyar with IPR’ (no love with intellectual property rights), rhymed some of the banners.

Affordable medicines produced in India have played a major role in scaling up HIV treatment to more than 6.6 million people across Asia, Africa and Latin America. By 2008, Indian generic antiretrovirals (ARVs) catered to 65% of total ARV purchases globally and 80% of donor-funded AIDS medicines. According to a 2011 policy brief issued by the Joint UN Programme on HIV/AIDS (UNAIDS), the UN Development Programme (UNDP) and the World Health Organisation (WHO), ‘increased availability of sources for generic medicines has drastically reduced the an-



Participants at a 10 February protest in New Delhi against the EU-India FTA make known their views.

nual price of first-line antiretroviral drugs from over \$10,000 per person in 2000 to less than \$116 for the cheapest WHO-recommended first-line antiretroviral regimen in the first quarter of 2010, a reduction of nearly 99%’.

The EU has repeatedly asked for IPR commitments that go way beyond India’s TRIPS commitments. This, analysts feel, will severely undermine the producing and marketing capabilities of the generic medicine industry in India and will threaten the access to cheap medicines worldwide. In a 10 February press release by several health groups, data exclusivity on medicines, intellectual property enforcement measures and investment protection are cited as some of the most damaging provisions that threaten access to medicines in India and the world. In addition, the EU also wants patent terms to be extended

from the current 20 years to 25 years. These provisions stand to further undermine access to medicines, which is already threatened by the current rules of international trade, the release pointed out.

Data exclusivity (DE), a key demand of the EU in this FTA, imposes strict restrictions on the use of trial data submitted by a company, notwithstanding whether a patent is granted to the company or not. In India, marketing regulators refer to such trial data to grant marketing licences to smaller generic companies for similar drugs. But DE, if agreed to, will imply that regulators cannot refer to trial data submitted by the original applicant to grant marketing rights to a generic producer for a certain period of time, usually 5-10 years or slightly more. So generic producers would have to repeat clinical trials and submit their own data if they want to

enter the market within this period. This is costly and often unaffordable for small producers and would in effect defer the introduction of cheap generics into the market. This also involves unethical wastage of resources in repeating trials of already established treatment. In Jordan, data exclusivity as a part of the US-Jordan FTA has raised medicine prices by 2 to 6 times, says a 2007 Oxfam study.

IP enforcement is another area of the FTA negotiations where the EU is demanding stringent provisions. According to a brief released by medical charity Medecins Sans Frontieres, the IP enforcement measures 'would widen the scope of actors that could have penalties brought against them and also increase the likelihood that wrongful searches, seizures and legal actions against legitimate suppliers of generic medicines will be carried out'.¹ First of all, the proposals in the FTA may extend stringent enforcement measures to cover 'patent infringements' (much more complex and difficult to determine) which were not covered under TRIPS. Second, the EU's proposed text also contains provisions that include third parties, and active pharmaceutical ingredient (API) manufacturers, drug distributors and treatment providers can be exposed to the risk of patent enforcement. The EU wants what are termed 'provisional injunctions', where courts are given powers to issue orders to prevent suspected but not yet proven infringement. Such threat of legal proceedings will deter many third parties from working with generic producers. The proposal also allows the possibility of issuing injunctions and seizing medicines on a mere suspicion or allegation of patent or trademark infringement and goes far beyond the provisions under the TRIPS Agreement. This can work as a major block for generic producers.

Such enforcement mechanisms also cover border measures which apparently establish stringency of IP standards of even goods in transit. This has recently become a highly controversial issue with the EU's repeated seizures of generic medicines

which were being transported from India to Brazil and other Third World countries through the Netherlands. The EU's border authorities seized these under EU Regulation 1383/2003 on grounds of 'patent infringement' – a charge strongly refuted by India – even though these were not meant for European citizens.

Demonstrations took place not only in Delhi but also in other countries where patients fear loss of access to crucial and cheap medicine supplies from India.

This case is under dispute settlement at the WTO and Canada, China, Ecuador, Brazil, Japan and Turkey have now joined the consultations.² India has alleged that 'such measures are inconsistent as such and as applied, with the obligations of the European Union and the Netherlands under Articles V and X of GATT [General Agreement on Tariffs and Trade] 1994 and under various provisions of the TRIPS Agreement, namely, Article 28 read together with Article 2, Articles 41 and 42, and Article 31 read together with the provisions of the August 2003 Decision on TRIPS and Public Health.' But such measures are often provided for in EU FTAs and undermine the supply of genuine and cheap medicines for treatment of critical diseases. The EU is very keen to include such measures under the FTA with India because it will give it considerable control over the movement of India's generic medicines.

Though the Indian government has announced it will not give in to TRIPS-plus demands from the EU, such demands seem to be very much on the table at the FTA negotiations.

Further, the EU also wants market access for its investors and investment protection at very high stand-

ards. India currently has bilateral investment treaties (BITs) with 22 EU member countries. Of these, the BIT with Germany offers the highest level of protection for foreign investors. The EU wants this level of protection for all member states under this FTA.

This will allow EU pharmaceutical companies to sue the Indian government in secret arbitration cases in international tribunals for huge sums of money under the investor-to-state clause. In the field of medicines, the definition of 'investment' will also compel the Indian government to recognise IPRs as an investment and therefore protect EU companies' IPRs (including data) under the investment protection clauses. This will erode the government's policy space and deter regulation of aggressive use of such IPRs in the interest of public health and access to medicines. The Uruguay government, for example, has been sued by Philip Morris, the tobacco company, when it tried to bring in legislation to allow more space for pictorial warnings on cigarette packages. In addition, if market access is given to European companies under the investment chapter, they will be free to invest in the Indian pharmaceutical industry without any performance requirements such as the need to incorporate local content in their production, and this will threaten the very existence of the Indian generic pharmaceutical industry.

Summit talks

The EU-India Summit on 10 February was expected to announce some kind of an understanding or perhaps set the broad terms of the FTA. Not surprisingly, protests by patients' groups reached a crescendo on the day. Demonstrations took place not only in Delhi but across the world, in Malaysia, South Korea, Thailand and in several African countries, all of which fear loss of access to crucial and cheap medicine supplies from India. A day earlier, activists had delivered coffins to the office of the European delegation to India.

The patients' groups were joined by farmers' groups from northern In-



A generics manufacturing unit on the outskirts of Mumbai. The intellectual property provisions demanded by the EU in the FTA negotiations could severely undermine the producing and marketing capabilities of the generic medicine industry in India.



The EU-India FTA could introduce data exclusivity provisions that impose strict restrictions on the use of data from clinical trials, thereby deferring the entry of generics into the market.

dia, dairy farmers from south India, small retailers, students and activists from all over, all of whom are severely worried about the impact of this FTA on the lives of ordinary people, including on their access to jobs, incomes, medicines, food, finance and natural resources... – the list seems endless but these concerns seem to be increasingly validated by the numerous reports and analyses pouring in.³

Apart from TRIPS-plus commitments in the IP chapter and a strong investment chapter, provisions in this FTA also include liberalisation of India's goods and services sectors including sensitive sectors like agriculture, retail, banking and key industries such as cars, as well as access to In-

dia's government procurement market. The vast multitude of the EU's demands in sensitive segments can severely threaten India's policy space and its development policy instruments.

During the Summit itself, however, leaders gave out no more than a broadly optimistic statement without going into specifics. India's Prime Minister Manmohan Singh said, 'There are obviously some problems but we are confident that those problems can be resolved and will be resolved. Both of us have reaffirmed our commitment to an agreement as early as possible.' The President of the European Council, Herman Van Rompuy, said the negotiations are

going well but also mentioned, 'We value substance over speed.' The European Commission President José Manuel Barroso seemed more optimistic and named Autumn 2012 as the target period to seal the deal. Leaders from both sides are now to supervise the negotiations closely so that an early agreement can be reached.

With global consciousness on critical development concerns around this FTA rising rapidly, there is increasing pressure on India and the EU not to make monumental mistakes that will threaten the health of people in India and the world. But in spite of the apparent show of understanding and reassurances, the EU is yet to give any substantial and lasting commitment that the provisions highlighted above will not be included in the FTA. It is clear that the people must continue to voice their strong concerns if the world is not to be deprived of affordable medicines. If global society does not play its role in protesting against such provisions, then in this labyrinth of shadowy deals and aggressive bargaining, the patients' voice may be lost forever. ♦

Ranja Sengupta is a senior researcher with the Third World Network.

Endnotes

- 1 http://www.msfaaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_FTAEnforcementProvisions_ENG_2012.pdf
- 2 The EU has recently offered a settlement and India and the EU have reached an 'understanding' and the EU has confirmed the detailed principles agreed in the understanding to guide border enforcement of intellectual property in the EU. The European Commission has also adopted a proposal for a new Regulation to replace Regulation 1383/2003 but India has not yet withdrawn the WTO case without making sure what the impacts of such legal changes will be. In any case, even after this 'understanding' Indian drugs were seized again by the EU.
- 3 For some of these, see <http://www.bilaterals.org> and <http://dontradeourlivesaway.wordpress.com/>

ACTA: undemocratic, dangerous and wrong

The European Parliament will be voting later this year on an Anti-Counterfeiting Trade Agreement (ACTA) which blurs the distinction between counterfeit and generic medicines by requiring customs officials to treat generic medicines as if they were counterfeit goods and seize them. Despite strong protests by civil society activists, the agreement has already been signed by several EU members and a number of other countries.

Charlie Harvey

IF, as Mark Getty famously claimed, 'intellectual property is the oil of the 21st century', then the Anti-Counterfeiting Trade Agreement (ACTA) has something of the character of a covert black-op in the 'oil' war. A covert black-op which will benefit corporate power. The whole thing has been negotiated in secret between rich countries in a policy-laundering scheme designed to avoid the meddlesome interference of democratic debate, transparency or dissent.

Like the recently defeated SOPA/PIPA legislation in the US, ACTA will introduce de facto censorship of the Internet, but ACTA goes one step further and introduces dangerous provisions that can be used by multinationals to restrict access to generic medicines to people in the Global South.

[Editor's note: The ACTA text was finalised in 2010. Australia, Canada, the European Union (and 22 member states), Japan, Morocco, New Zealand, Singapore, South Korea and the US have signed the agreement, which will enter into force following ratification by six signatories.]

Lobbyists for Big Pharma have added their own clauses into the agreement that require customs officials to treat generic medicines as if they were counterfeit goods and seize them.

'Negotiating countries are cynically using legitimate fears of counterfeit medicines to exert greater con-



A protester at an anti-ACTA demonstration in Warsaw. ACTA can be used by multinational drug companies to restrict access to generic medicines.

trol over the trade in generic medicines to poor countries,' says Oxfam spokesperson Rohit Malpani. 'ACTA is proposing a new, expanded framework of intellectual property protections on behalf of multinational drug companies which will be combined with border measures to stifle the trade in legitimate generic medicines. This will mean that poor people will be denied legitimate and life-saving generic medicines.'

The obfuscatory tactic of intentionally confusing one thing with another is nothing new on behalf of the multinationals. In



A research laboratory of an Indian generic medicine producer. 'ACTA is proposing a new, expanded framework of intellectual property protections... which will be combined with border measures to stifle the trade in legitimate generic medicines.'

fact the whole notion of intellectual property is deeply problematic, confusing as it does the three very different phenomena of copyright, patents and trademarks. Throwing counterfeiting into the mix bamboozles even more. Now, it suddenly becomes possible to talk about countries trying to save lives as if they were some geezer selling knock-off Rolexes down the market. Or to speak of people who share ideas, computer code or music as 'pirates'.

The World Health Organisation (WHO) estimates that 1.3 to 2.1 billion of the poorest people in the world do not have access to essential medicines. There is something deeply wrong in a society that values the profits of a global corporation more highly than securing that access. At least 20 legitimate shipments of life-saving generic medicines have already been seized under a similar EU regulation. ACTA will formalise and extend that power. It's not clear that it will do anything to prevent the circulation of fake medicines.

'We are in danger of ending up with the worst of both worlds,' says Michelle Childs of Medecins Sans Frontieres, 'pushing IP [intellectual property] rules, which are very effective at stopping access to life-saving drugs but are very bad at stopping or preventing fake drugs.'

ACTA's censorship provisions are also extremely troubling. Like SOPA/PIPA, they introduce virtual fiefdoms for copyright holders, encouraging a chilling effect on freedom of expression online.

'The ACTA enforcement regime imposes a nineteenth-century view of intellectual property (IP) that fails to acknowledge the changed relationship between individuals and information in the modern electronic age,' says human rights group Article 19. 'Consequently, the IP interests of corporations are disproportionately protected at the expense of individuals' rights to freedom of expression and information.'



Participants at a signing ceremony for ACTA held in Tokyo last October. The ACTA negotiations had largely been shrouded in secrecy, lacking in public scrutiny.

Perhaps the most controversial aspects of ACTA are its intentional avoidance of the usual norms of democratic accountability and introducing a parallel legislative process. As Adam Ma'anit, writing before the treaty was finalised, noted in the September 2010 issue of *New Internationalist* magazine: 'ACTA is being negotiated in secret between supposedly democratic entities ... while some cursory information has been released, there is still concern over the substance of the negotiations and the

lack of public debate and scrutiny over some of its more odious details.' The process has consistently excluded civil society groups, and even parliamentary discussion.

We all need to stop ACTA before it's too late. ♦

Charlie Harvey is the IT Manager for New Internationalist magazine. He is active in both the activist and tech communities and is a vocal advocate of free software. The above is an edited version of an article which appeared on the New Internationalist blog. Reproduced by kind permission of New Internationalist. Copyright New Internationalist. www.newint.org

The case against ACTA

• **While it is claimed that ACTA will protect against falsified medicines by allowing countries and companies to take strong measures in trademark disputes, this may in fact impede access to genuine generic medicines.**

There are several issues here. First, not all trademark disputes amount to a public health problem. Only 'wilful trademark counterfeiting on a commercial scale' – a form of fraud with a deliberate intention to exactly copy a product's branding – presents a legitimate public health

concern. The World Trade Organisation itself distinguishes between 'trademark counterfeiting' and 'trademark infringement'. This means that trademark infringement disputes that companies may have over similar names or packaging by competitors cannot be considered as trademark counterfeiting.

But ACTA blurs this distinction. This means it would require countries to impose stringent intellectual property enforcement measures for civil trademark confusion disputes. Worryingly, disputes over allegations of

similar-sounding names or packaging are common in the medicines field, as companies will often choose brand names for medicines that sound inevitably similar, in that they are derived from the drug's international non-proprietary name (INN). Similar names and packaging are often even desirable to demonstrate medical equivalency, but they do not mean that the medicines are unsafe or indeed that there has been a trademark infringement.

ACTA even extends enforcement to patent challenges. These IP infringements are generally commercial disputes where no inherent public health concerns exist. While patents and protection of undisclosed information are explicitly excluded from the border measures and criminal enforcement sections of the agreement, significantly reducing the negative effects on access to medicines, a number of provisions apply to patents and data protection as the default position, although signatories to ACTA 'may exclude' them. As has been noted, this suggests that such exclusion should be the exception and not the norm, and it is highly likely that such distinctions will be blurred in the course of negotiations with developing countries.

Lastly, ACTA's civil enforcement section may also allow expanded enforcement efforts based on fictional patent claims. These efforts favour rights holders and contain few if any safeguards for defendants or third parties.

- **ACTA allows the border detention of in-transit medicines destined for developing countries, which will interfere with the trade in legitimate medicines, and leaves trade in generic medicines open to disruption.**

While the border measures section of ACTA no longer includes patents, it still includes civil trademark infringement. This means a customs official could decide to detain and even destroy an allegedly infringing good – without any court oversight or even notification to the rights holder or the generic company alleged to have violated the trademark – on

the basis of the customs official's own view on whether the goods in question infringe a commercial trademark.

The risks to access to medicines of such overbroad provisions have been recently highlighted when medicines were detained in Germany based

Under ACTA, even legitimate medicines just transiting through an ACTA member country could be temporarily or permanently seized.

on the wrong assumption that a generic medicine, using the required international non-proprietary name 'amoxicillin' to describe the contents, infringed GlaxoSmithKline's trademark on the brand name Amoxil (which besides is itself a use of the INN). At the core of this detention was an expansive EU customs regulation designed to expand the enforcement of IP rights that led to many other detentions of medicines in transit between developing countries which were not IP-protected in the source or destination countries.

Under ACTA, too, even legitimate medicines just transiting through an ACTA member country could be temporarily or permanently seized. *Ex officio* mechanisms without judicial review – and allowing the detention, seizure, and even destruction of goods – are susceptible to over-enforcement. Civil trademark infringement is a very grey area of fact and degree that requires judicial oversight to resolve. It is not appropriate for untrained border guards acting *ex officio* to make determinations that courts are best suited to make – particularly in cases where the result of these determinations would be the denial of medicines to patients.

Rights holders could also use border measures as a commercial tactic to delay or destroy rivals' goods on a mere allegation of similar names, without a health threat, before a court

hearing to determine whether their claim is in fact valid.

ACTA expands also the TRIPS requirement on border measures for import to cover export as well. For countries which are exporters of generic medicines for the developing world, the application of border measures to exports threatens to disrupt the lifeline for patients.

- **ACTA acts as a deterrent to the production and trade in generic medicines, as it provides for excessive punishment, shifts the risks entirely on to the generic manufacturer, and grants few protections against abuse.**

ACTA is imbalanced. On a mere allegation and not proof, including allegation brought by a competitor, generic suppliers allegedly infringing a trademark and potentially a patent may face the delay or destruction of goods, disproportionate damages, potential bankruptcy, and in some cases, even criminal proceedings.

The severe punishment for infringement obstructs and deters legitimate generic competition by dramatically altering the risks faced by generic medicines manufacturers, intermediaries and third parties. By generally focusing on harsh remedies before infringement has been proven, ACTA seeks to shift the risk on to the generic manufacturers rather than waiting until the IP holder has proved its case. The possibility of issuing injunctions and seizing medicines on a mere suspicion of infringement is extremely problematic and goes beyond what is required under the TRIPS Agreement. This will have a chilling effect on the manufacturers of generic medicines.

Further, ACTA provides great incentives for abuse because of the greater access to information and the potential for competitive advantage, coupled with limited liability for abuse. There are few penalties for false accusations, and few protections for the alleged infringer. ♦

This is extracted from 'A blank cheque for abuse: The Anti-Counterfeiting Trade Agreement (ACTA) and its impact on access to medicines', a briefing paper (updated February 2012) published by Medecins Sans Frontieres' Access Campaign.

The compulsory licence on sorafenib: A right step to ensure access to medicines

The decision by the Indian Patent Office to grant a local company a compulsory licence to produce a generic version of an anti-cancer drug patented by Bayer on the grounds that it was not available at a 'reasonably affordable price' is a major step to ensure access to medicines.

KM Gopakumar

THE Indian Patent Office (IPO) made a landmark order on 12 March to grant domestic drug company Natco Pharma a compulsory licence (CL) to produce the generic version of multinational pharmaceutical firm Bayer's anti-cancer medicine sorafenib.

This order would allow sorafenib to be made available for Rs8,800 (\$173.93) per box that contains 120 100 mg tablets for a month's treatment, against Bayer's price of Rs280,000 per box.

However, Natco is not the first generic company to bring this medicine at a lower price. India's leading pharmaceutical company Cipla had introduced its generic version earlier, only to be subjected to a patent infringement suit by Bayer. The Patent Office order now ensures that low-cost sorafenib would be available in India even if Bayer wins the patent infringement suit. Further, Natco's price is even lower than Cipla's price of Rs28,000 per pack.

Background

Sorafenib is used to treat primary kidney cancer (renal cell carcinoma, RCC) and advanced primary liver cancer (hepatocellular carcinoma, HCC) that cannot be removed by surgery. It can extend the life of kidney cancer patients by 4-5 years and of liver cancer patients by 6-8 months.

Bayer obtained the marketing approval for sorafenib in 2005 and launched the drug worldwide in 2006 under the brand name Nexavar. Total sales of sorafenib in 2009 were \$934 million.

Bayer charges an exorbitant price for this life-saving medicine. As a result, the UK National Institute of Clinical Excellence rejected sorafenib for National Health System (NHS) use in England, Wales and Northern Ireland, saying that the cost of the drug does not justify the benefit. Citing the same reason, the Scottish Medicines Consortium refused the use of sorafenib within NHS Scotland. However, the incremental benefit of the medicine is considered valuable.

In India, Bayer obtained the patent for sorafenib on 3 March 2008. The company supplied the medicine to the Indian market by importing it from its German manufacturing facility.

Natco filed its application for a compulsory licence under Section 84(1) of the Indian Patents Act on 29 July 2011. Section 84(1) allows any interested party to make a CL application after the expiration of three years from the date the patent was granted. The application can be made on three grounds: (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied; (b) that the patented invention is not available to the public at a reasonably affordable price; (c) that the patented invention is not worked in the territory of India. However, Section 84(6)(iv) also insists that, prior to the CL application, the applicant should make efforts to obtain a voluntary licence from the

patentee on reasonable terms and conditions; six months is provided as a reasonable time period for such efforts. Natco initiated the CL process by seeking a voluntary licence through a letter dated 6 December 2010 and received a refusal letter from Bayer on 27 December 2010.

Decision

Through an order dated 11 August 2011, India's Controller of Patents, the head of the Patent Office, stated that after 'careful consideration of the Application I am of the view that a *prima facie* case, under Section 87(1) of the Patents Act 1970, has been established'. Further, the Controller directed Natco to serve a copy of the CL application to Bayer to initiate CL proceedings.

[Section 87(1) of the Patents Act states: 'Where the Controller is satisfied, upon consideration of an application under Section 84, or Section 85, that a *prima facie* case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the Official Journal.']

Bayer attempted to delay the proceedings by approaching the courts to challenge the Patent Controller's order. Bayer stated that the Controller had not given Bayer an opportunity to present its views before making the order. The Mumbai High Court re-

refused to hear the petition, citing jurisdiction, and directed Bayer to approach the Delhi High Court. (It is learned that even though Bayer approached the Delhi High Court, it subsequently withdrew the petition without pressing for an order.)

Natco in its CL application stated that Bayer was supplying the medicine through imports and failed to take adequate steps to manufacture the product in India. As a result, the medicine was available only in limited quantities through pharmacies attached to a few big hospitals in four cities, Chennai, Delhi, Kolkata and Mumbai. Further, Natco mentioned that Bayer was charging an exorbitant price for the medicine and made the product out of reach of most of the people who needed it.

Natco also cited six reasons to show the failure of Bayer to satisfy the reasonable requirements of the public with respect to the patented invention. They were: (a) refusal of request for a voluntary licence under reasonable terms and conditions; (b) failure to adequately meet the demand for the patented product; (c) exorbitant prices made the product out of reach of the common man, hence a failure to meet the demand for the product on reasonable terms; (d) non-working of the patented invention in India; (e) limited supply of the patented product through selective sources; and (f) abuse of monopoly rights by charging an exorbitant price.

Further, Natco stated that it could produce and market the medicine for Rs8,800 per month per person. It also stated that sorafenib would be made available free of cost to deserving and needy patients.

On the first ground [under Section 84(1)] of whether Bayer failed to satisfy the reasonable requirements of the public with respect to the patented invention, the Controller stated in his March decision that ‘the Patentee’s conduct of not making the drug available as per the requirements of public in India during four years, since the grant of patent, is not at all justifiable’. The Controller further stated, ‘It is also not the case of the Patentee that there is no demand for the drug

because as per their own submission, there is a requirement for at least 8842 patients. Even after the lapse of three years, the Patentee has imported and made available only an insignificant proportion of the reasonable requirement of the patented product in India.’

On the second ground of whether the patented invention is not available to the public at a reasonably affordable price, the Controller decided that ‘during the last four years the sales of the drug by the Patentee at a price of about Rs280,000 (for a therapy of one month) constitute a fraction of the requirement of the public. It stands to common logic that a patented article like the drug in this case was not bought by the public due to only one reason, i.e., its price was not reasonably affordable to them. Hence, I conclude beyond doubt that the patented invention was not available to the public at a reasonably affordable price and that Section 84(1)(b) of the Patents Act 1970 is invoked in this case’.

On the argument of Bayer that affordability is required to be considered with regard to different classes/sections of the public, the Controller stated that ‘I fully agree with the Patentee. I only wonder why the Patentee did not execute this concept by offering differential pricing for different classes/sections of public in India’.

On the third ground of whether the patented invention is not worked in the territory of India, the Controller said, ‘It is an admitted fact that the Patentee does have manufacturing facilities for manufacturing drugs in India, including oncology drugs. However, even after the lapse of four years from the date of grant of patent, the Patentee failed to do so ... Accordingly, I hold that Section 84(1)(c) is attracted in this case and consequently a compulsory licence be issued to the Applicant under Section 84 of the Act.’

However, some of the conditions imposed on Natco are onerous in nature. For instance, one of the conditions is that the licence ‘is granted solely for the purpose of making, using, offering to sell and selling the

drug covered by the patent for the purpose of treating HCC and RCC in humans within the Territory of India’. The licensee must also ensure, among others, that its product is ‘visibly distinct from the licensor’s product (e.g. in colour and/or shape); the trade name must be distinct, and the packaging must be distinct. The licensor will provide no legal, regulatory, medical, technical, manufacturing, sales, marketing, or any other support of any kind to the licensee’. These conditions are imposed on the licensee without any statutory basis. Care should be exercised that such conditions are not attached to future CLs.

Implications on access to medicines

Often pharmaceutical multinational corporations (MNCs) misuse their patent monopoly to charge exorbitant prices and undermine local production through importation. The sorafenib CL disrupts this type of abuse because the Patent Office ordered its issuance on the ground of absence of affordable price and local manufacturing. In other words, the CL makes it difficult for MNCs in the coming days to charge exorbitant prices for patented medicines and to meet developing-country market needs through importation. Thus this licence opens the door to curbing such abuses of patent monopoly. This is an opportunity for other developing countries to invoke compulsory licensing on the same grounds.

The sorafenib licence is believed to be the first of its kind issued in a developing country in response to an application filed by a generic manufacturer since the World Trade Organisation (WTO)’s international Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into force. Even though developing countries have granted over 50 CLs in the last 16 years – especially after the 2001 Doha Declaration on the TRIPS Agreement and Public Health reaffirmed WTO member states’ right to use flexibilities (like compulsory licensing) enshrined in the TRIPS Agreement – these licences

were issued under the ‘government use’ format, not at the request of a generic medicine company.

In the past, pharmaceutical MNCs and developed countries mounted economical and political pressures against the issuance of CLs. For instance, drug giant Abbott withdrew the registration of nearly 12 medicines from Thailand after the issuance of a ‘government use’ order in that country. The Trade Commissioner of the European Union wrote a letter to Thailand stating that the latter’s decision to invoke ‘government use’ provisions was illegal.

In the case of the present licence, the US Commerce Secretary has already conveyed the US’ concerns on the CL issuance. However, unlike in the ‘government use’ format, the present CL was issued after a quasi-judicial process and the executive branch of the state had little role in its issuance. Therefore the external pressure may not have the desired effect on CL issuance.

Most importantly, this CL proves that generic pharmaceutical companies can use compulsory licensing to supply important patented medicines at an affordable price. A business model based on TRIPS flexibilities, especially compulsory licensing, can be adopted to ensure access to new medicines and also to encourage local production in developing countries.

It may also have the effect of forcing pharmaceutical MNCs to change their behaviour towards developing countries in order to avoid the issuance of CLs. For instance, Roche has already announced its decision to cut the prices of two cancer medicines, trastuzumab (brand name: Herceptin) and rituximab (Mabthera), which are used for the treatment of breast cancer and cancers of the lymphatic system known as non-Hodgkin’s lymphomas. The current prices of these medicines are \$300 and \$4,500 per month per patient. As per Roche’s announcement, the Indian pharmaceutical company Emcure would repack the medicines and market them in India. Interestingly, Roche has yet to reveal the discounted prices, hence

it is too early to make a judgement on this decision.

However, analysts point out that one cannot expect substantial price reductions in such dealings; otherwise, it would put the MNCs on the defensive with regard to the exorbitant prices in developed countries. Therefore, these analysts dismiss the Roche announcement as merely an attempt to preempt the threat of compulsory licensing. Further, the developing countries should not be swayed by such differential pricing decisions. It is important for them to determine the affordability of the medicines in relation to the socioeconomic conditions of each country, rather than simply accepting the quantum of any price reduction announced by the MNCs.

Resource to compulsory licensing

Besides sorafenib, there are many more patented medicines which are sold at exorbitant prices in India. In the absence of a credible public sector capability in pharmaceutical production, access to affordable medicines in India is completely dependent on the ability and willingness of the private sector to make use of compulsory licensing provisions.

However, whether more Indian pharmaceutical companies would come forward to apply for CLs depends on many other factors. There are two important factors, namely, alliances with MNCs and exposure in developed-country markets. Currently, many Indian drug companies have strategic alliances with pharmaceutical MNCs, primarily for contract manufacturing. These companies may not want to get on the wrong side of Big Pharma by seeking CLs. Similarly, companies which derive a large portion of their revenues from developed-country markets might be reluctant to use CLs for fear of a backlash in these markets.

Furthermore, not all companies are in a position to use CLs to introduce generic versions, because developing the product requires technological capabilities. MNCs may also pre-

vent companies from using CLs through a carrot-and-stick approach. The ‘carrot’ could come in the form of a voluntary licence (with restrictive conditions), a strategic alliance or an offer to buy out the company at a high price. The ‘stick’ may be wielded through a series of litigations and propaganda against these companies globally.

In any case, the issuance of a CL by the Patent Office may not be the end of the story; it could instead mark the beginning of a protracted legal battle in the courts. For instance, Bayer has already made known its intention to challenge the latest decision of the Patent Office before the appropriate forum. Thus only companies with the resource base and patience can make use of CL provisions.

Further, there are still legal uncertainties in the compulsory licensing provisions of the Patents Act. These include the lack of a time limit to dispose of CL applications and of a ceiling on royalties to be paid to the patentee, and the stringent conditions accompanying CLs. Such uncertainties may deter companies from having recourse to compulsory licensing. Therefore, further finetuning of the legal provisions, through amendments or rules or precedents, is required to increase the level of confidence among applicants.

Lack of information may also hinder potential CL applicants. Often a single medicine would be covered with multiple patents; hence it is important to identify the relevant patents prior to lodging an application. Smaller pharmaceutical companies may find it difficult to obtain such information.

Therefore, developing-country governments like the Indian government need to address the abovementioned issues through legal and policy tools to create an enabling environment for domestic pharmaceutical companies to make use of CL provisions. However, the immediate task is to vehemently resist anti-CL propaganda and potential legal challenges to CL provisions at national and international forums. ♦

The dangerous myths of Fukushima

Although all the available evidence that has emerged in the year after the Fukushima disaster has confirmed that it was a major nuclear accident, officials are still attempting to downplay its health consequences.

Joseph Mangano and Janette Sherman

THE myth that Fukushima radiation levels were too low to harm humans persists, a year after the meltdown. A 2 March 2012 *New York Times* article quoted Vanderbilt University professor John Boice: 'There's no opportunity for conducting epidemiological studies that have any chance for success – the doses are just too low.' Wolfgang Weiss of the UN Scientific Committee on the Effects of Atomic Radiation also recently said that doses observed in screening of Japanese people 'are very low'.

Views like these are political, not scientific, virtually identical to what the nuclear industry cheerleaders claim. Nuclear Energy Institute spokesperson Tony Pietrangelo issued a statement in June that 'no health effects are expected among the Japanese people as a result of the events at Fukushima'.

In their haste to choke off all consideration of harm from Fukushima radiation, nuclear plant owners and their willing dupes in the scientific community built a castle against invaders – those open-minded researchers who would first conduct objective research *before* rushing to judgment. The pro-nuclear chants of 'no harm' and 'no studies needed' are intended to be permanent, as part of damage control for a dangerous technology that has produced yet another catastrophe.

But just one year after Fukushima, the 'no harm' mantra is now being crowded by evidence – evidence to the contrary.

First, estimates of releases have soared. The first reports issued by the

Japanese government stated that emissions equalled 10% of 1986 Chernobyl emissions. A few weeks later, they doubled that estimate to 20%. By October 2011, an article in the journal *Nature* estimated Fukushima emissions to be more than double those of Chernobyl. How anyone, let alone scientists, could call Fukushima doses 'too low' to cause harm in the face of this evidence is astounding.

Where did the radioactive particles and gases go? Officials from national meteorological agencies in countries like France and Austria followed the plume, and made colourful maps available on the Internet. Within six days of the meltdowns, the plume had reached the US, and within 18 days, it had circled the Northern Hemisphere.

How much radiation entered the US environment? A July 2011 journal article by officials at Pacific Northwest National Laboratory in Washington State reported measurements of airborne radioactive xenon-133 up to 40,000 times greater than normal in the weeks following the fallout. Xenon-133 is a gas that travels rapidly and does not enter the body, but signals that other, more dangerous types of radioactive chemicals will follow.

A February 2012 journal article by the US Geological Survey looked at radioactive iodine-131 that entered soil from rainfall, and found levels hundreds of times above normal in places like Portland, Fresno and Denver. The same places also had the



Residents of Fukushima prefecture being tested for radiation exposure in the aftermath of the March 2011 nuclear catastrophe. Estimates of radiation releases have soared in the one year since the disaster.

highest levels of caesium-134 and caesium-137 in the US. While elevated radiation levels were found in all parts of the country, it appears that the West Coast and Rocky Mountain states received the greatest amounts of Fukushima fallout.

Radiation in rainfall guarantees that humans will ingest a poisonous mix of chemicals. The rain enters reservoirs of drinking water, pastures where milk-giving cows graze, the soil of produce farms, and other sources of food and water.

Finally, how many people were harmed by Fukushima in the short term? Official studies have chipped away at the oft-repeated claim that nobody died from Fukushima. February brought the news that 573 deaths in the area near the stricken reactors were certified by coroners as related to the nuclear crisis, with dozens more deaths to be reviewed. Another survey showed that births near Fukushima declined 25% in the three months following the meltdowns. One physician speculated that many women chose to deliver away from Fukushima, but an increase in stillbirths remains as a potential factor. In British Columbia, the

number of Sudden Infant Death Syndrome deaths was 10 in the first three months after Fukushima, up from just one a year before.

On 19 December 2011, we announced the publication of the first peer-reviewed scientific journal article examining potential health risks after Fukushima. In the 14-week period 20 March-25 June 2011, there was an increase in deaths reported to the Centers for Disease Control and Prevention by 122 US cities. If final statistics (not available until late 2014) confirm this trend, about 14,000 'excess' deaths occurred among Americans in this period.

We made no statement that only Fukushima fallout caused these patterns. But we found some red flags: infants had the greatest excess (infants are most susceptible to radiation), and a similar increase occurred in the US in the months following Chernobyl. Our study reinforced Fukushima health hazard concerns, and we hope to spur others to engage in research on both short-term and long-term effects.

For years, the assumption that low-dose radiation doesn't harm people has been used, only to fall flat on its face every time. X-rays to abdomens of pregnant women, exposure to atom bomb fallout, and exposures to nuclear weapons workers were all once presumed to be harmless due to low dose levels – until scientific studies proved otherwise. Officials have dropped their assumptions on these types of exposure, but continue to claim that Fukushima was harmless.

Simply dismissing needed research on Fukushima health consequences because doses are 'too low' is irresponsible, and contradictory to many scientific studies. There will most certainly be a fight over Fukushima health studies, much like there was after Chernobyl and Three Mile Island. However, we hope that the dialogue will be open-minded and will use evidence over assumptions, rather than just scoffing at what may well turn out to be the worst nuclear disaster in history. ♦

Joseph Mangano is an epidemiologist and Executive Director of the Radiation and Public Health Project in the US. Janette Sherman is an internist and toxicologist. This article is reproduced from CounterPunch.org.

Unpacking the Issue of Counterfeit Medicines

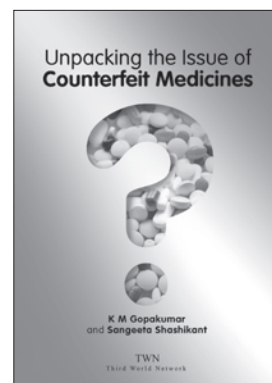
KM Gopakumar & Sangeeta Shashikant

Numerous anti-counterfeiting initiatives driven by an intellectual property enforcement agenda have emerged in international organisations.

The World Health Organisation has also accelerated action against 'counterfeit medicines', through the International Medical Product Anti-Counterfeit Taskforce (IMPACT). The WHO's approach has resulted in concerns that legitimate generic medicines may get caught up in the web of definitions and enforcement of 'counterfeit products', with adverse consequences for access to medicine as well as legitimate trade.

This book discusses the background to the issue of 'counterfeit medicines' in the WHO as well as the problems of using the term 'counterfeit' (in connection with intellectual property rights violations) to refer to products with compromised quality, safety and efficacy issues against a background of anti-counterfeiting initiatives in the context of IP enforcement aggressively being pushed by businesses and governments of the Organisation for Economic Cooperation and Development (OECD).

The book also discusses origins of the IMPACT and analyses issues and concerns about the Taskforce



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pertaining to legitimacy, transparency, accountability, links to IP enforcement, and the creation of barriers to trade in, and access to, affordable generic medicines.

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Japan's remarkable renewable energy drive – after Fukushima

Since the Fukushima disaster a year ago, Japan has taken some important strides in its drive for alternatives to nuclear energy. *Andrew DeWit* provides an account of these changes.

THE looming shutdown of every single one of Japan's nuclear plants – previously the providers of nearly one-third of the nation's electricity – has accelerated the country's initiatives on conservation, renewable energy sources, and decentralisation of electricity supply. It has also injected considerable momentum into Japan's 'green cities' initiative.

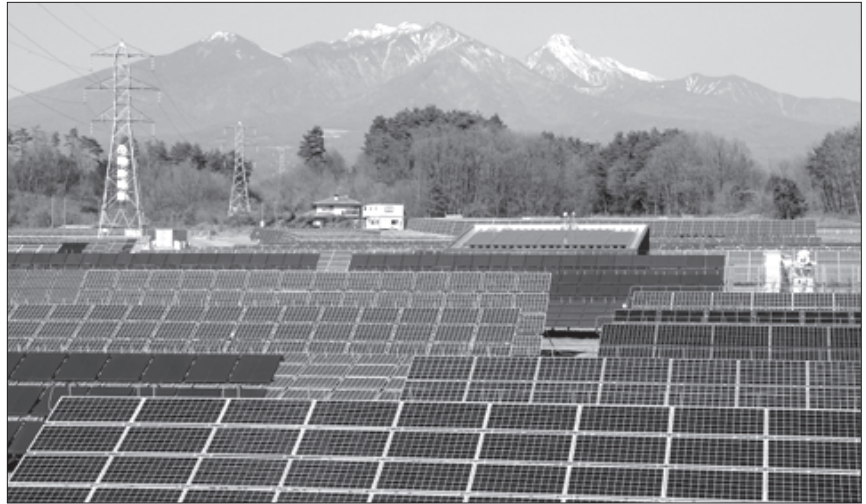
These changes are being fought by those who insist that Japan cannot live without nuclear power. The opponents include not just the utilities, but the banks who lent so much to the utilities, Keidanren (the main business federation) and much of the national government.

However, the growing cost of energy and worries about power supply are pushing firms and local governments to find alternatives. Japan responded with surprisingly rapid success in conservation and efficiency after the oil crises of 1973 and 1979. It may do so again.

Nuke shutdown

At present, only one of Japan's 54 nuclear reactors is operating, and it is scheduled to go offline in early May. Minister of Economy, Trade and Industry (METI) Edano Yukio says that Japan seems likely to spend this summer with no nuclear reactors in operation at all.

Japanese reactors have regular, 13-month maintenance schedules, and the approval of national and local authorities is required before they can be restarted. In order to reassure a newly resistant public of their safety, the nuclear reactors were subject to new 'stress tests' as of last year. But in late February, the stress tests were publicly deemed inadequate by



Solar panels at an experimental solar power generation plant in Hokuto, Japan. Japan has increasingly robust policies in place for diffusing renewable energy alternatives like solar power.

Madarame Haruki, Chairman of the Nuclear Safety Commission and a long-time proponent of nuclear power. That criticism has only increased opposition to restarts by prefectural governors, who are in a position to veto them. Even supportive local leaders are now calling for a resolution of the waste-storage problem before any restarts are allowed.

Buying expensive carbon fuels

To make up for the shortfall, a lot of gas, oil and coal-fired power capacity is being ramped up, newly deployed or taken out of mothballs. Data from METI indicates that in December 2011 thermal power composed 86% of power generation, with 16% of that being oil-fired, 23% coal and 46% Liquefied Natural Gas (LNG). Nuclear reactors provided only 7.4% of total power. Compare that with April, when nuclear was 28.2% of power generation, and thermal power

(5% oil, 20% coal, 38% LNG) was 63% of the remainder.

Japan's total fuel imports in 2010 were valued at ¥17.4 trillion (\$217 billion) but increased by 25% to ¥21.8 trillion in 2011. Some was due to an actual increase in volume and some to sharp price increases. In any case, the imports rose from 3.6% of GDP to 4.6%. The increased costs seem likely to continue for the foreseeable future. As a result, the much-loathed utility TEPCO (Tokyo Electric Power Corporation) is slated to raise electricity prices for large-lot power consumers (those using more than 500 kilowatts) by an average of 17%.

Pushback by nuclear lobby

These threatened price increases have mobilised a significant pushback by Keidanren-centred business interests that still view the nuclear reactors as a cheap source of safe, reliable, low-emissions power and want them restarted. Their desire dovetails

with that of the three big financial institutions which hold trillions of yen in loans to TEPCO, the biggest slice in the corporate bond market, as well as financing for other utilities.

Their nightmare scenario surely envisions Japan making it through a nuclear-free summer with no major blackouts or supply-chain disruptions. Such a scenario would perhaps tip opinion towards seeing nuclear energy as dispensable even in the short term, and thus lead to trillions of yen in stranded assets.

The banks have tried to forestall this outcome by securing reactor restarts as a precondition for their advancing any additional finance to a nationalised TEPCO. The financial sector and many large-lot power consumers have put forward a tsunami of arguments that the electricity price increases, resulting from costly purchases in international markets, and uncertainty of supply will exacerbate Japan's already grim problem of hollering out. Japan's rising yen, shrinking population, huge public-sector debt and other handicaps already pose significant disincentives to business investment, and the power issue clearly does not help.

Conservation: a different answer

While some push nuclear restarts as the answer to the problems of availability and cost, others are accelerating moves towards greater energy efficiency and conservation as well as creating big incentives for the rapid deployment of renewable power. There were startling advances in conservation and energy efficiency last year, driven by compulsory power reductions as well as subsidies and other encouragement.

For example, a recent study by market research firm GfK reported that less than 2.2% of household ceiling lights were LED (light-emitting diodes) in January of last year, but by the week of 13-19 February of this year LED lights had taken a 49.4% share of the market. Falling prices through this mass production also bode well for Japanese electronics

makers hard-pressed in international markets by the strong yen.

The power-consumption data suggest policy support for efficiency had significant effects. The figures of the Federation of Electric Power Companies in Japan (FERC) for the summer months of 2011 show total nationwide electricity sales, relative to the previous year, down 5% in July, 11.3% in August and 11.4% in September. Data for January 2012 indicate that power generation was down 3.7% compared to January of 2011.

Conservation and efficiency were already a growth industry before the nuclear crisis. But the new, unforeseeable spurs to innovation and diffusion may see Japan overshoot 'New Growth Strategy' targets for 2020. These were established in June 2010, and aim at a 'green innovation' market totalling ¥50 trillion (\$625 billion, or 10% of 2011 GDP) and 1.4 million new workers.

One example of the growing scale of the conservation incentives is that 80% of 104 major Japanese firms surveyed in late February by the *Yomiuri* planned to reduce power purchases from TEPCO. More than half (54) of the firms declared that they would invest in conservation, and 14 of the 104 replied that they would deploy some form of in-house power-generation capacity. To respond to this increasing demand for conservation, firms are rushing energy management systems to market. Toray Engineering, for example, announced 29 February that it was opening sales on its 'Eco-Plant EMS', an energy management system for use in factories. The system comes with a ¥40 million (\$500,000) price tag, but in on-site tests apparently achieved a 30% power reduction of air conditioning and a 10-20% reduction in factory power use overall.

Moving to renewables

Moreover, Japan has increasingly robust policies in place for diffusing renewable alternatives. In particular, its feed-in tariff (FIT) – a long-term subsidy guaranteeing producers a certain rate on the supply of electricity –

has been expanded from solar to include wind, biomass, small hydro and geothermal, and will take effect by 1 July.

Price setting and periods of guarantee are being determined by a five-member consultative committee that held its first meeting on 6 March. The pro-renewable majority on the committee suggests these crucial elements of the policy will be robust, perhaps driving rapid diffusion and concomitant price declines in this market as well. Marubeni, NTT, Mitsui, and a host of local governments and other organisations are already committed to large-scale mega-solar, wind and related projects. The most recent data indicate that the total of mega-solar projects announced over the past year is twice what the utilities were planning to install up to 2020. This is strong evidence of how much low-hanging fruit there was in Japan on renewables. We seem likely to find a similar story in efficiency and conservation.

Decentralisation

Local governments have been particularly aggressive in responding to the crises driven and exacerbated by the Fukushima shock. The effective collapse of national energy policy has seen many rethink their growth strategies and revamp their intergovernmental organisations, both among themselves as well as between them and the central government. The Fukushima shock was profound for most local governments due to the existential threat to power supplies as well as the central government's abysmal crisis management in the weeks following the disaster.

Major local governments such as Metropolitan Tokyo and Osaka are especially concerned by their vulnerability to highly centralised power generation and transmission as well as its clearly incompetent governance by the national administration. One of their responses to this threat from centralised, overly complex energy institutions dominated by vested interests has been to increase local resilience and autonomy via decentralised

power generation. Tokyo, for example, determined that it needed its own generation capacity in order to maintain subway transport and other critical functions in the event of an emergency. So it is installing gas-fired power and a small-scale smart grid separate from the TEPCO utility. Also, Osaka City and Osaka Prefecture have banded together to launch an energy commission, which met on 27 February. They are explicitly committed to ramping up conservation and renewables in the face of the central government's immobilism. Kobe and Kyoto have joined Osaka as partners in the effort.

Other prefectures, including Kanagawa and Saitama, are also explicitly aiming their policymaking at efficiency and fostering an energy shift to renewable power so as to enhance self-reliance, employment and business opportunities, as well as international competitiveness. As of late February, local governments' Fiscal 2012 initial budget compilations had a combined ¥52 billion (\$650 million) investment aimed at fostering renewable power projects. While not tallied yet, the locals' investments in conservation and energy efficiency are many multiples of the budget for renewables. The central government's feed-in tariff adds to these kinds of generalised incentives to enhance local resilience.

National government divided

The central government seems deeply conflicted. On the one hand, it appears to be waiting for a crisis in power supply to drive restarts. On the other hand, it is using the ongoing crisis to act rapidly to reshape the power economy and thus leverage green growth prospects. So, Prime Minister Noda Yoshihiko, partial to the Ministry of Finance and the banks, repeatedly calls for restarts while distracting himself with crafting visions for raising the consumption tax, though such fiscal austerity killed a recovery back in 1997. And his METI Minister Edano announced in a 26 January press conference that restarts might be unavoidable, yet failed to

outline any serious initiatives for further incentivising efficiency. Surely both understand that the longer they dawdle, allowing uncertainty free rein, the more damage is done to incentives to invest in Japan. As we have seen repeatedly over the past year, the nuclear lobby will say almost anything to keep their assets from becoming stranded. And that is what they are doing now, while the Noda Cabinet is preoccupied with papering over its divisions.

However, at the same time, central agencies are also rushing to keep up with events by deregulating so as to foster new industry as well as to open farmland, waterways and parks to renewable power projects. Among recent moves, METI is indicating that it will exempt solar from the factory site regulations on green space as well as include solar in calculations of peak-power supply. Even the EU countries don't do the latter as their peak demand is at night. But Japan's peak is in daytime in the summer due to air-conditioning demand, and this coincides well with peak insolation and solar output. Also, the Ministry of Agriculture, Forestry and Fisheries recently announced 1,000 regional sites for small hydro and other renewable projects. There is more than a little irony in seeing the political class that was elected on a promise to displace bureaucrats being outclassed by them in a crisis.

New deregulatory efforts

These new deregulatory efforts are worth watching. They carry on from the flagship comprehensive special zone law, which was passed on 22 June 2011. The zone initiative was billed as a means to 'concentrate resources of central and local government in areas of high pioneering potential'. It is not simply a relaxation of rules but also an overall package of support that includes regulatory exemptions, tax breaks, financial aid and loans and other mechanisms aimed at innovation.

The major types of comprehensive special zones are the international strategic zones and the regional re-

talisation zones. The strategic zones are aimed at clustering industry and related intellectual and other resources so as to increase growth opportunities in the environment, next-generation energy, bio life science, and other areas. These zones include a 'Green Asia International Strategy comprehensive special zone', which groups Fukuoka City and Prefecture with Kitakyushu City in an initiative to position their region in western Japan as the gateway to Asia.

There were seven strategic zones as of February 2012. In total, they comprise budgetary requests of ¥153.9 billion (\$1.9 billion) which are expected to lead to ¥6.97 trillion (\$85 billion) in new economic activity and 298,000 new jobs.

There are at present 26 regional revitalisation zones. The ambit of this zone programme includes disaster prevention and mitigation, environment and next-generation industry, tourism and culture, agriculture, biomass, finance and social business, healthcare and nursing. The total fiscal scale of the zones is ¥63 billion (\$0.7 billion) that is expected to lead to ¥2.15 trillion (\$26 billion) in new business activity and 67,000 new jobs.

The tax breaks in the international strategic zones are focused on lowering the corporate tax in order to foster competitiveness in international markets, while those in the regional revitalisation zones centre on deductions for individual investment in enterprises that are part of the strategy.

Green cities initiative

This flurry of deregulation policies is increasingly being funnelled into the larger environmental 'future city' initiative. This latter policy regime carries on from the 'eco-model city' programme that was put in place in the summer of 2008, and has helped environmental award-winning cities like Kitakyushu in Fukuoka Prefecture deepen their green business and expand their overseas sales. Kitakyushu last year became the first Asian city for the OECD's Green City Programme. It is also exporting its expertise on recycling to such Chinese

cities as Dalian and Qingdao. And it is expanding its reach in the global water business that in 2007 was assessed at ¥36.2 trillion (\$440 billion) and is expected to reach ¥86.5 trillion (\$1.05 trillion) in 2025. Kitakyushu's water-management business is finding purchasers in Cambodia's Phnom Penh as well as Vietnam's Hai Phong. The future city policy that Kitakyushu is part of was adopted as one of the 21 national strategic projects of the 'New Growth Strategy' passed on 18 June 2010.

This initiative is not simply for green growth; it also includes measures for dealing with rapidly aging societies and disseminating policy lessons learned from within the eco-model cities. The initiative seeks synergies among these categories as well as from among the recipient cities. On 22 December, 11 cities were selected as eco-model cities. Five were outside of Tohoku, the area hit by the earthquake. These five include Kitakyushu and Yokohama among those previously designated as eco-model cities. But after 11 March 2011, the national authorities expanded the group to include six from the affected area. These six cities include hard-hit Minamisoma and Kamaishi.

The inclusion of these cities in the larger initiative indicates that the government is drawing on outstanding successes of the eco-model city initiative, and expanding it to devastated areas. These successes include the realisation of targets for such aspects as recycling, international engagement, and the demonstration of energy management systems. The core devastated areas are being rebuilt as renewable-centred smart cities with funding from the ¥19 trillion (\$237 billion) fund for reconstruction. Japanese policymakers clearly see including them in the overall green city project as a way to encourage application of lessons learned from both the cities initially involved in the eco-city project as well as those that are trying to rebuild from the tsunami. It is a means of speeding the dissemination of policy learning among local governments in general as well as to overseas markets.

Japan seeks lead in new global market

Japan is seeking to use its policy tools and experience as a means to gain leadership in the export of green city models. This is a new and rapidly growing market. The University of Westminster's authoritative International Eco Cities Initiative reports that its most recent (September 2011) international survey found 'an unprecedented mushrooming of various kinds of eco-city initiatives and projects across the world', with a total of 174 eco-city projects catalogued.

Japan's initiative is not just a bureaucratic talking shop. The eco-city initiative was institutionalised on 14 December 2008 and included 140 organisations. Of these organisations, 70 were 'highly motivated municipalities', along with 39 prefectures, 12 related government ministries and 19 related organs of government. As of November 2011, these ranks had swelled to 89 cities, 46 prefectures, 12 governmental offices, 29 public organisations, and 28 organisations from the private sector for a total of 204 organisations. The private sector members include Japan IBM, Mitsubishi Automobiles, Pacific Consulting, and Nikkei BP. The latter is very strongly interested in a global 'smart city' market that it expects to reach a cumulative ¥4,000 trillion (\$49 trillion) by 2030.

The tug of war

To what extent will these nice-sounding initiatives actually bear fruit? That remains to be seen. But to make an assessment of the chances, we need to get back to the context for all these policy moves. The potential for a zero-nuclear summer certainly presents risks to Japan. But it also affords an opportunity to ramp up the diffusion of cutting-edge conservation and renewable technologies as well as to accelerate other focused action in this existing set of policies for fostering sustainable growth in green cities.

With powerful pressure from

subnational governments, the green cities policy regime may become the agency for driving the Japanese political economy onto a sustainable growth track. The more Japan is pressed to rapidly innovate models of green city growth, the greater its prospects of realising the national strategy of expanding green city exports.

The problem with implementing this national strategy hitherto has been the enormous weight of vested interests in the power and Keidanren-centred manufacturing sector. They seek to shape green growth to accord with their own institutional interests which have long been bound up with nuclear power and TEPCO. Among other unwise things, that meant maintaining power monopolies and suppressing the diffusion of renewables and smart grids. Such interests are incompatible with the most competitive and sustainable green city model. Rather, the weight of vested interests has threatened to produce something of a 'Galapagos effect', referring to an environment found nowhere else, giving Japan a hamstrung green city model unsuited to most of the potential green city markets in rapidly growing Asia and other regions.

But with the FIT and local initiatives, some of Japan's most innovative providers of capital, including Softbank, have increasingly robust incentives and opportunities to wreak creative destruction in power and other strategic markets. Through deploying the most advanced technology and business practices, they increase the pressure on others, including the central government, to move faster and smarter. Perhaps this conjunction of daunting incentives and capable players in Japan's power sector can help make the country's green city policy regime truly world-class. ♦

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Going nuclear? Malaysians voice concern over move

Moves by the Malaysian authorities to embark on nuclear energy as an alternative have touched off a debate in the country. *Fauwaz Abdul Aziz* reports on a public forum which explored the issues at stake.

DESPITE the ideal scenarios portrayed and the attractive narratives and economic models shown by proponents of nuclear energy as a source of supply for the country's electricity demand, Malaysians made it abundantly clear at a recent forum that they were well aware that the actual story of nuclear energy as borne out by its track record stands in stark contrast.

At a 16 February forum on 'Nuclear Energy as an Option for Malaysia' – organised at the Institute of Diplomacy and Foreign Relations in Kuala Lumpur by the United Nations Association Malaysia, Association of Former Malaysian Ambassadors and Malaysian Physicians for Social Responsibility – the audience made clear their sentiments about the matter.

After a whole day of hearing both sides of the debate, the moderator for the last panel discussion, World Islamic Economic Forum secretary-general Ahmad Fuzi Haji Abdul Razak, asked the floor as to how many in the auditorium were in support of the development of nuclear energy in Malaysia.

Less than 20 people in the roughly 350-member audience raised their hands.

When Fuzi asked how many were in opposition to developing nuclear capability to address Malaysia's growing energy needs, however, everyone else in the hall showed their opposition to the nuclear option.

Proponents present their case

Earlier, in his opening remarks to the forum, president and CEO of national energy firm Tenaga Nasional Berhad (TNB), Che Khalib Mohamad Noh, said he wanted the audience to go home with three points in their

minds:

- An energy crisis is facing Malaysians as local resources are depleting, there is an increased dependency on imported fuels, and those imported fuels are getting more expensive;

- Since Malaysia has been inviting industries which are energy guzzlers as investments into the country, this worrisome trend would increase the country's energy demand, hence planning is needed for a more 'balanced' development in relation to energy supply and consumption to distribute the risks, to open up to all possible technologies and energy resources, including nuclear, to develop the country's power system, 'especially nuclear'; and

- More needs to be done, 'especially in terms of policy and commercial mechanisms', for the efficient use of energy.

Che Khalib showed that electricity demand in Malaysia is on the rise, having gone from a weekly peak demand of 14,245MW in the last quarter of 2009 to 15,476MW in May 2011. This is expected to rise to more than 16,000MW in 2012, and to 20,847MW in 2020, said Che Khalib, and will continue to grow by about 3% every year until 2030 when it will reach 24,770MW.

With fossil fuels currently constituting 94% of the total energy generation mix, there needs to be greater diversification of power supply sources. While renewable energy (RE) sources such as solar, biomass, biogas, hydro and solid waste are viable options, those options are limited. Solar power and biogas suffer from relatively high capital costs, biomass fuel supply security is questionable, both biomass and mini-hy-

dro plants are usually located far from load centres, while there is the issue of emission waste plaguing solid waste plants due to the status of the technology, Che Khalib said, adding that RE as a whole lacks a centralised base-load capacity.

He also emphasised what he claimed were the superior features of the nuclear option, such as its 'longer fuel cycle', its unparalleled fuel cost as well as its 'relatively very low or non-existent emissions' relative to other energy sources.

Acknowledging public concerns over the 'Three Mile Island, Chernobyl and Fukushima incidents', the long construction time (between 10 and 15 years) and considerable investment that nuclear power plants entail, the issues over radioactive waste, the possibility of terrorist attacks on nuclear facilities and nuclear weapons development, Che Khalib also said the government is aware of the need for public acceptance, stringent regulatory imperatives, site preparation and manpower development.

But if nuclear power were to be ruled out completely because of the few accidents that have occurred and the losses incurred as a result thereof, then that would also preclude the use of air travel on account of the few incidents of aircraft disasters, said Che Khalib. Compounding this attitude was the lack of trust in Malaysian technicians and engineers to ensure the safety of the public, he added.

'If that's the case, then nobody would be flying planes. There are Malaysian engineers and technicians who are maintaining some of the planes that we fly on,' he argued.

Following Che Khalib, the CEO

of the one-year-old Malaysian Nuclear Power Corporation (MNPC) Dr Mohd. Zamzam Jaafar gave further details on the deployment of 'Nuclear Energy for Power Generation'. He stressed that since Malaysia has positioned itself to be a developed nation within eight years, the nuclear option was necessary to address the mid- and long-term demands of such a goal.

In contrast with the rising prices of fossil fuels, nuclear fuel is low-cost – 'between 2 to 3 cents' per kWh – stable despite the need to continually import uranium, and friendly to the environment as a result of low greenhouse gas emissions, said Zamzam.

Zamzam reiterated that:

- the government had announced on 26 June 2009 that it had designated nuclear energy as one of the options for electricity generation;

- going nuclear was identified in 2010 as one of the 12 Entry Point Projects (EPP) under the oil, gas and energy sector according to guidelines, covering 19 key areas, set by the International Atomic Energy Agency (IAEA);

- the MNPC had, since its establishment on 7 January 2011, been assigned the role of spearheading, planning and coordinating the implementation of a nuclear energy development programme;

- a nuclear power pre-feasibility study had been jointly conducted by TNB and the Korea Electric Power Corp, and an 'initial site selection' had already been made (A copy of the final report was submitted to the government on 15 July 2010, but when questioned later by a participant as to who now holds this study and whether it was available to the public, both Che Khalib and Zamzam were unable to give a concrete answer);

- a Nuclear Power Infrastructure Development Plan is being prepared for completion by 2013; and

- a steering committee is looking into the possibility of at least one of a twin-unit 2-gigawatt nuclear power plant, with construction of the first unit beginning by 2014, and the commission of that plant by 2021.

Zamzam also stressed, however, that a feasibility study will be carried

out on the 'final' selected nuclear power plant site, including lessons learned from the Fukushima incident of 2011 as well as the reactor technology options, and that the bid document will be the basis to invite potential turnkey nuclear power plant vendors to bid only if a final decision is taken to 'go nuclear' in 2014. Zamzam argued that nuclear power is a valid energy option if there are suitable sites for nuclear power plants, strong community support, and the backing of the IAEA.

Promise vs. reality

Following Zamzam, it was for Indian journalist and anti-nuclear power activist Dr Praful Bidwai to unravel the picture of nuclear energy as being cheap, reliable, economically viable and the answer to climate change.

Nuclear power has been promoted, Bidwai argued in his presentation entitled 'A Bleak Future for the Global Nuclear Industry', only by way of 'utopian assumptions' and the lofty promise of universal prosperity.

Since the launch of the 'Atoms for Peace' plan in 1953 and the creation of the IAEA, the world has seen only 'untested premises', 'huge state subsidies', misrepresentation, 'democratic deficits' and disasters of catastrophic proportions, said Bidwai, a founding member of the Coalition for Nuclear Disarmament and Peace in India.

In his own country, said Bidwai, he has seen over the past decades the same promises extended by the proponents of nuclear energy in Malaysia betrayed by the reality of an industry that survives on secret and opaque decision-making, the running up of astronomical expenses borne by public funds, devastating accidents, and the spewing out of dangerous radiation.

'By the early 1980s, nuclear power had clearly failed "the market test". Soon, with Chernobyl of 1986, it would also fail the test of safety and popular acceptance. A year earlier, *Forbes* magazine had called nuclear

power "the biggest managerial disaster in history",' said Bidwai.

He also cited energy expert Amory B Lovins as having termed nuclear power as 'the greatest failure of any enterprise in the industrial history of the world'. The nuclear industry 'had lost more than \$1 trillion in subsidies, cash losses, abandoned projects and other damage to the public', he added.

Fukushima is only the latest disaster in an industry where accidents, when they happen, are catastrophic in scale.

Recounting the stagnation of nuclear generation capacity over the past 20 years, Bidwai noted that the number of operating reactors as of April last year was 437, compared to 444 in April 2002.

Nuclear power output has annually declined by 2% over the past four years and now only accounts for about 13% of the world's electricity generation and 5.5% of commercial primary energy – and just 2% of final energy consumption.

Contradicting claims of its low costs, Bidwai said nuclear power is considerably more expensive than most other fuels, while its capital costs have more than doubled over the past decade.

'When the costs of decommissioning and waste storage are added, the unit costs become astronomical. Nuclear power has survived only because of state support, including caps on liability for accidents', which he described as 'ridiculously low' relative to the actual costs when a nuclear disaster occurs.

Recounting the dozens of disasters such as Kyshtym in 1957, Three Mile Island in 1979 and Chernobyl in 1986, Bidwai said Fukushima is only the latest in an industry where accidents, when they happen, are cata-

strophic in scale.

Nuclear power is the only mode of energy generation that can have catastrophic accidents, resulting in severe health and environmental damage and overwhelming economic losses, said Bidwai.

‘Nuclear reactors are complex, internally, tightly coupled systems.... Accidents are inevitable in nuclear reactors. Their probability may be low, that must be admitted, but their consequences are enormous.’

Aside from the human disasters, the environmental and economic damage from a single nuclear accident is ‘unconscionably high’ and runs into hundreds of billions of dollars.

The global nuclear industry never fully recovered from Chernobyl’s political, psychological and economic effects, with the US Scientific Committee on the Effects of Atomic Radiation estimating that apart from radiation-induced cancers and leukaemias, there have been additional cancers numbering anywhere between 34,000 and 140,000.

Speaking on Fukushima, Bidwai said the world witnessed not one but three core meltdowns before its very eyes, with the effects of the accident continuing up until today. Citing the Swiss investment bank UBS, he said: ‘At Fukushima, four reactors have been out of control for weeks – casting doubt on whether even an advanced economy can master nuclear safety ... We believe the Fukushima accident was the most serious ever for the credibility of nuclear power.’

Fukushima will almost certainly exacerbate the global nuclear industry’s crisis and accelerate its decline. Bidwai went on to describe nuclear power and nuclear weapons as ‘Siamese twins’ that share much of the same infrastructure: ‘Nuclear electricity generation always poses the danger of proliferation of mass-destruction weapons, and of sabotage and conventional attacks on nuclear installations, with horrifying consequences.’

The Japanese government, meanwhile, has only given an ‘irresponsible response’ to the nuclear meltdown in its refusal to tell the public the truth,

its failure to monitor radiation levels and its collusion with the nuclear industry, while still struggling to evacuate and resettle the hundreds of thousands of its people affected by the incident.

As such, Bidwai concluded, nuclear power cannot be a solution to the energy crisis in Malaysia, particularly, nor to the crisis of climate, generally.

‘Its potential contribution is far too small, it is too slow to deploy, and too expensive, to be a real candidate. By contrast, renewables have already emerged as a safe, flexible, quickly deployable solution, which typically have a lower carbon footprint than nuclear power.

‘Nuclear power can have no place in the new system... Secrecy, centralised decision-making, collusion between industry and government – is this the development you want that you thrust down the throats of people who don’t want it?’

United Nations Resident Coordinator for Malaysia, Kamal Malhotra, addressed the role of the IAEA in promoting the peaceful use of nuclear energy and against nuclear weapons in his presentation.

The increasing demand for energy and the drive towards economic development have had negative impacts on the environment and quality of life.

As for nuclear energy, while the social objectives of sustainable development have to be met, people must not lose sight of the need for democratic decision-making, including having open debates on all issues related to nuclear energy.

Although the Malaysian government says RE sources may not be able to meet the country’s rising energy demand, they should be more seriously explored and promoted, especially given their abundance and relative affordability in Malaysia, said Malhotra.

Viable, available alternatives

Following Malhotra, two scientists presented papers that, for all their technical content and subject matter,

drove the point across that a number of alternatives were available to address all of the concerns raised by proponents of the nuclear option over the needs of people for energy. Some had already seen success and only needed parties that were willing to experiment and invest their time and resources to see it happen.

Associate Professor Mark Diesendorf of the Institute of Environmental Studies at the University of New South Wales in Australia, in his presentation on the technological status and economics of nuclear and renewable sources of electricity, reiterated the risks of nuclear energy:

- the risks of nuclear proliferation through uranium enrichment and reprocessing of spent nuclear fuel;
- targeting by terrorists;
- long-term management of high-level and low-level nuclear wastes; and
- devastating nuclear accidents, as in Chernobyl and Fukushima.

He said the Japan Centre for Economic Research had estimated the Fukushima disaster as having loaded the Japanese people with a burden of \$71-\$250 billion, which is only part of the cost of compensation.

As for the current global status of nuclear energy, Diesendorf said that 437 reactors were operating in 30 countries after a peak of 444 reactors in 2004, while the proportion of nuclear to total electrical energy generation had declined substantially from 17% in 2001 to 13% last year. Many reactors, he noted further, are expected to be retired over the next two decades.

Diesendorf also pointed to the enormous, time-consuming and capital-intensive resources that go into nuclear power plant construction, and said that during the process delays are frequent and cost overruns balloon along with increasing interest payments. The experience in Australia has shown that RE projects, on the other hand, can be planned, approved and installed within two to three years.

Diesendorf said he and fellow researchers had in their work proven that RE can meet 100% of Australia’s electricity demand using commer-

cially available technologies such as wind, PV concentrating solar thermal (CST) power with thermal storage, hydro and biofuels.

The main challenge they found was in meeting peak demand on winter evenings, but even this can be addressed by bio-fuelled gas turbines and managing demand.

Malaysia could take the initiative by way of efficient energy use, the use of solar technology such as solar PV with optional battery storage for evening peak demand, base-load or peak-load electricity from biomass, use of mini-hydros, going geothermal and long-term future trade in RE, such as solar hydrogen.

Associate Professor Feroz Kabir Kazi from the University of Nottingham (Malaysia campus), similarly, presented on the case for renewable energy, specifically bioenergy. Malaysia, he pointed out, has a power generation capacity of 24,000MW based on a supply mix of natural gas (61%), coal and peat (31%), hydro (3%), and oil (2%).

Reiterating Che Khalib's note that 94% of power in Malaysia is generated from fossil fuels, Feroz showed however that Malaysia has yet to tap its rich renewable energy resources, as RE has an electricity production potential of 11,742MW, of which 5,000MW could come from biomass alone.

To boost development, the feed-in-tariff mechanism had recently been introduced. Feroz also showed that even a small 10MW biomass-based steam-Rankine cycle power plant model could, by combustion of oil palm empty fruit bunches, produce electricity at the rate of 29 cents per kWh.

While RE has a future in Malaysia, the country needs to commit and directly subsidise and develop RE technologies such as mini-hydro, solar and geothermal energy technology. If that happens, Malaysia can have energy security and sustainable development. Development of the RE industry could also create opportunities to boost local employment and economic growth, said Feroz.

'The facts are in the public domain'

In his concluding remarks, president of Malaysian Physicians for Social Responsibility Dr Ronald S McCoy expressed what the overwhelming majority in the audience evidently felt by the end of the day: Notwithstanding TNB's Che Khalib's ideas of what he wanted the audience to go home with, it was the compelling evidence of the nuclear industry's destructive potential that they most likely had in mind rather than the hopes of nuclear proponents that benign use of it would proceed without incident.

'The nuclear industry and other vested interests in some corporate and academic sectors have been disseminating disinformation to an uninformed Malaysian public, although it is patently clear that nuclear energy is unsafe, unaffordable and unacceptable.'

'The recent catastrophic nuclear accident in Fukushima has been a wake-up call for countries operating nuclear power plants and for those planning to build their first nuclear reactors. Many are phasing out nuclear power and turning to renewable energy, energy efficiency and energy conservation,' said McCoy.

'So why has the Malaysian government not followed other countries in renouncing nuclear energy and turning to research and development of sustainable renewable energy and energy efficiency technologies?' he asked.

'Malaysians deserve a forthright answer from the government, especially when the facts of nuclear energy and renewable energy are clearly in the public domain,' he asserted, pointing out:

- the costs of nuclear energy, not including the 'huge, hidden subsidies' which will impoverish social programmes for health, education and other social needs;

- that since 2002, the costs of nuclear energy have escalated rapidly while the costs of renewable energy have been declining;

- Malaysia has significant RE resources which offer clean energy, greater local employment and rapid deployment; and

- a sustainable energy mix could provide sufficient power and create many more jobs.

In a nutshell, said McCoy, the only viable option for Malaysia is to put aside nuclear energy and invest in renewable energy and energy efficiency.

'The reality is that if medieval Man had used nuclear energy, today we would still be managing his nuclear waste.'

The greatest objection to nuclear energy, however, is the inability to safely dispose of nuclear waste which remains radioactive for tens of thousands of years, said McCoy.

'Radiation is treacherous and causes cellular mutation, which can be transmitted to future generations and cause birth defects and cancer.'

'Plutonium has a half-life of 24,400 years. In other words, it will take 24,400 years for the radioactivity of any quantity of plutonium to be halved. As nuclear waste cannot be permanently disposed of safely, it will have to be "managed temporarily" for at least 100,000 years. In other words, the poison of radioactive waste will be with us "forever". And yet, there is no social institution on the planet that has lasted for more than 2,000 years.'

'The reality is that if medieval Man had used nuclear energy, today we would still be managing his nuclear waste. To bequeath such a lethal legacy to future generations of Malaysians is unconscionable, unethical and immoral. Malaysia must not countenance nuclear energy and betray future generations of Malaysians. We must reject nuclear energy,' said McCoy.

'Do you think that nuclear energy is reliable, affordable, economically viable, socially acceptable and environmentally sound? Not many Malaysians will be in a position to answer that question with confidence.'

Fauwaz Abdul Aziz is a researcher with the Third World Network.

The fable of the century

In the following satirical piece by *Robert B Reich* on the US presidential campaign, the target is the Republican Party and its likely presidential candidate, Mitt Romney.

IMAGINE a country in which the very richest people get all the economic gains. They eventually accumulate so much of the nation's total income and wealth that the middle class no longer has the purchasing power to keep the economy going full speed. Most of the middle class's wages keep falling and their major asset – their home – keeps shrinking in value.

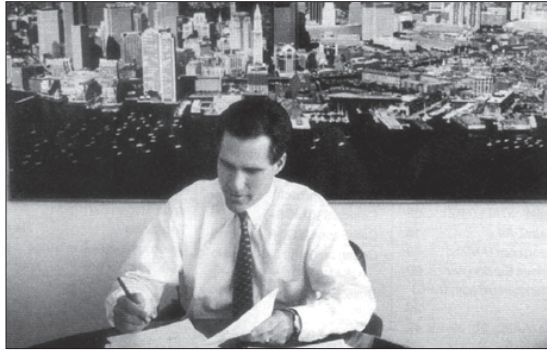
Imagine that the richest people in this country use some of their vast wealth to routinely bribe politicians. They get the politicians to cut their taxes so low there's no money to finance important public investments that the middle class depends on – such as schools and roads, or safety nets such as health care for the elderly and poor.

Imagine further that among the richest of these rich are financiers. These financiers have so much power over the rest of the economy they get average taxpayers to bail them out when their bets in the casino called the stock market go bad. They have so much power they even shred regulations intended to limit their power.

These financiers have so much power they force businesses to lay off millions of workers and to reduce the wages and benefits of millions of others, in order to maximise profits and raise share prices – all of which make the financiers even richer, because they own so much stock and run the casino.

Now, imagine that among the richest of these financiers are people called private-equity managers who buy up companies in order to squeeze even more money out of them by loading them up with debt and firing even more of their employees, and then selling the companies for a fat profit.

Although these private-equity managers don't even risk their own money – they round up investors to buy the target companies – they none-



'[I]magine... a presidential election [where] one party... nominates as its candidate a private-equity manager who has raked in more than \$20 million a year and paid only 13.9% in taxes...' Picture shows Republican Party presidential candidate Mitt Romney in his earlier years as a private-equity manager.

theless pocket 20% of those fat profits.

And because of a loophole in the tax laws, which they created with their political bribes, these private-equity managers are allowed to treat their whopping earnings as capital gains, taxed at only 15% – even though they themselves made no investment and didn't risk a dime.

Finally, imagine there is a presidential election. One party, called the Republican Party, nominates as its candidate a private-equity manager who has raked in more than \$20 million a year and paid only 13.9% in taxes – a lower tax rate than for many in the middle class.

Yes, I know it sounds far-fetched. But bear with me because the fable gets even wilder. Imagine this candidate and his party come up with a plan to cut the taxes of the rich even more – so millionaires save another \$150,000 a year. And their plan cuts everything else the middle class and the poor depend on – Medicare, Medicaid, education, job-training, food stamps, Pell grants, child nutrition, even law enforcement.

What happens next?

There are two endings to this fable. You have to decide which it's to be.

In one ending the private-equity manager candidate gets all his friends

and everyone in the Wall Street casino and everyone in every executive suite of big corporations to contribute the largest wad of campaign money ever assembled – beyond your imagination.

The candidate uses the money to run continuous advertisements telling the same big lies over and over, such as 'don't tax the wealthy because they create the jobs' and 'don't tax corporations or they'll go abroad' and 'government is your enemy' and 'the other party wants to turn America into a socialist state'.

And because big lies told repeatedly start sounding like the truth, the citizens of the country begin to believe them, and they elect the private-equity manager president. Then he and his friends turn the country into a plutocracy (which it was starting to become anyway).

But there's another ending. In this one, the candidacy of the private-equity manager (and all the money he and his friends use to try to sell their lies) has the opposite effect. It awakens the citizens of the country to what is happening to their economy and their democracy. It ignites a movement among the citizens to take it all back.

The citizens repudiate the private-equity manager and everything he stands for, and the party that nominated him. And they begin to recreate an economy that works for everyone and a democracy that's responsive to everyone.

Just a fable, of course. But the ending is up to you. ♦

*Former US Secretary of Labour Robert B Reich is Chancellor's Professor of Public Policy at the Goldman School of Public Policy at the University of California at Berkeley. He has written 13 books, including his latest bestseller, *AfterShock: The Next Economy and America's Future*, and his newest, an e-book, *Beyond Outrage: What Has Gone Wrong with Our Economy and Our Democracy, and How to Fix It*. This article is reproduced from his website robertreich.org.*

Bahrainis demand more than cosmetic reforms

Months after an independent commission presented damning evidence of the Bahraini government's crackdown on pro-democracy demonstrators, thousands press on with a reinvigorated protest movement for genuine reform.

David Elkins

IN March, an estimated 100,000 civilians filled the streets in what, according to observers, were the largest demonstrations the gulf nation of Bahrain has experienced since protests began last year.

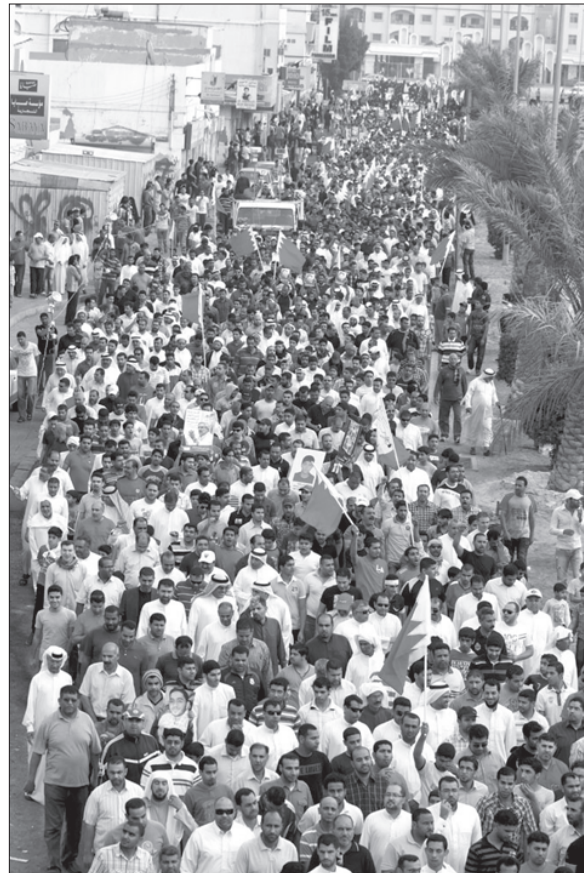
The continued crackdown on the near-daily protests since then prompted a UN condemnation on 20 March of the Bahraini security officials' 'disproportionate use of force' to suppress protesters.

On the same day, the Bahrain Centre for Human Rights, one of the few human rights advocacy groups operating in the country, released evidence of the deaths of two civilians in mid-March from tear gas asphyxiation.

'Since 23 November, when the King received the Bahrain Independent Commission on Inquiry report, there have been 31 civilian deaths that were allegedly caused by unrest, and zero deaths of members of the security forces,' Bill Marczak, director of Bahrain Watch, a human rights watchdog and advocacy group, told Inter Press Service (IPS).

'Three of the deaths seem to be attributable to long-term declines in physical or mental health that may have been caused by unrest before 23 November,' he said.

The Bahraini government has restricted entry for journalists and human rights observers, as independent witnesses continue to document abuses, including torture, arbitrary detention, sexual harassment, beatings, and a growing number of deaths



Pro-reform protesters taking to the streets of Bahrain.

and serious injuries from rubber bullets and tear gas, some of which are supplied by US manufacturers.

'While the US has paused a 53-million-dollar arms sale to Bahrain, other smaller arms sales are ongoing, and the US government still apparently issues licences for direct commercial sales of tear gas and other items to Bahrain,' Marczak said.

'[T]here has been no known investigation of the use of likely US-origin weapons against protesters, such as M113 APCs fitted with .50

calibre M2 Browning machine guns that were used last year...The use of these weapons against unarmed protesters is likely violation of US law, and in violation of the end-use conditions agreed to when the M113s were originally donated to Bahrain at little or no cost in the 1990s and 2000s under the Excess Defence Articles programme.'

Dwindling prospects

The commission was funded by the Bahraini government and chaired by M Cherif Bassiouni, a professor of international human rights law at DePaul University. Despite its findings, which contained unequivocal evidence of human rights abuses and made recommendations for reform, the likelihood for genuine reform or a political settlement seems to be dwindling, according to analysts.

Earlier this year the Bahraini government resumed trials, after indicating that the charges would be dropped, of 20 doctors who were indicted for fomenting armed insurrection against the government and subsequently received sentences from five to 15 years after supposedly forced confessions from torture.

According to Brian Dooley, a Human Rights First observer who witnessed their appeal trials in mid-March, the defendants were not given permission to field all of the witnesses for their defence, this coming after government prosecutors supplied 'unpersuasive' video footage of am-

balances that allegedly proves that weapons were 'being ferried to protesters'.

Bahraini diplomats have followed King Hamad bin Isa al-Khalifa's lead in showering praise on the steps his government has taken towards political and human rights reform.

'Over 10 years ago, His Majesty the King instituted a reform process that has brought meaningful change to Bahrain. And despite assertions to the contrary, this process has never stopped,' the Bahraini Ambassador to the US Houda Nonoo wrote on her blog on 21 March.

In a display of good faith, Bahraini officials announced on 22 March that cameras would be installed in prisons to help dissuade abuse of detainees.

'On balance, these steps taken so far and promised are welcome and we should look at them seriously and see how far they go. However, there are a number of problems... They are clearly trying to convince the world that the situation is not as bad as it sounds,' Joost Hiltermann, a regional expert at the International Crisis Group, said at a recent conference.

Opposition groups have coalesced around a common enemy in the al-Khalifa government but disagreements over, for instance, whether a negotiated settlement with the monarchy or a complete overthrow of the current government's grip on power will suffice, have embedded a competitive dynamic for the loyalty of the protesters and the various ethnic, re-



The government of King Hamad bin Isa al-Khalifa (pic) has restricted entry for journalists and human rights observers, even as independent witnesses continue to document rights abuses.

ligious and political groups in the country.

As entrenched political factions within the Bahraini government, representing Sunni Islamists and supporters of the powerful Prime Minister Sheikh Khalifa bin Salman al-Khalifa, continue to thwart attempts at genuine reform, many are left questioning whether any of the recommendations in the commission's report will be implemented in the foreseeable future.

'One tactic that seems to be used by Bahrain's government to avoid giving up power is to build barriers of fear and intolerance between different groups of people (Sunni vs. Shia, expatriates vs. locals, citizens vs. police) to prevent them from realising common ground and achieving the more effective, accountable and transparent governance that they all want,' Marczak said.

'How does Bahrain begin taking

those steps? It's difficult to say, but I think the solution is continued pressure, both through monitoring and other forms of activism, and direct pressure from foreign governments and ordinary Bahrainis.'

Political reform

Several experts remain convinced that regardless of any improvements made in protecting human rights, a lasting solution will be difficult without political and social reforms, including genuine dialogue, government accountability, ethnic and religious integration of the security and military forces and institutional reform of the electoral and judicial systems.

'What we really need is political reform. Even if all these human rights reforms are implemented, we will be back, more or less, to the status quo ante of 11 February 2011. Which, of course, that situation was unsustainable, hence the protests,' Hiltermann said.

'It is a matter both of the international regional situation and the local situation converging in a particular good constellation. Right now I don't see it, frankly.'

In an interview with *jadaliyya.com* on 22 March, a spokesperson for the Coalition of February 14 Youth, a decentralised opposition group in Bahrain, echoed the sentiment that deeper changes will be necessary.

'The first and foremost goal that revolutionaries are struggling for is the liberation of our land from Saudi occupation and the overthrow of the al-Khalifa regime, which has lost its popular and constitutional legitimacy,' the spokesperson said.

'Once that is achieved, the people can choose their own destiny and choose the political and economic system that meets their ambitions and aspirations. We will not under any circumstance accept a compromise with this bloody regime that continues to violate our human rights. We are determined to liberate our precious homeland from dictatorship, and build a nation of justice, dignity, and equality for all its citizens.' — IPS ♦



A riot police officer firing tear gas at Bahraini protesters. Human rights groups have released evidence of civilians dying from tear gas asphyxiation.

Remembering Domitila: Making Bolivian history

A tribute to Domitila Barrios de Chungara, the long-time Bolivian social activist, feminist and mine union leader whose 1978 hunger strike is credited with bringing down a dictatorship and changing the course of Bolivian history.

Emily Achtenberg

BOLIVIANS paid tribute to Domitila Barrios de Chungara, long-time social activist, union leader, feminist, revolutionary and national heroine who died 13 March in Cochabamba at age 74. She is best known as the miner's wife who led a hunger strike in 1978 that brought down the dictatorship of General Hugo Bánzer, paving the way for the return of Bolivian democracy.

'The democracy that we have been living since 1982 is thanks to Domitila,' said Filemón Escobar, an original founder and ex-Senator of the Movement towards Socialism (MAS) party. President Evo Morales declared three days of national mourning and Domitila was posthumously awarded the Condor of the Andes honour, the highest distinction the state can confer on a Bolivian citizen.

Repression and struggle

Domitila's life is a testimony to Bolivia's tragic history of exploitation, repression, colonialism, and patriarchalism, but also to the power of ordinary people to demand and effect change. Born in 1937 in Potosí, then the largest tin-producing region of Bolivia, she was the daughter and wife of a miner. Losing her mother at age 10, she raised five younger sisters and then seven surviving children of her own under conditions of extreme deprivation and poverty.

In the 1960s, Domitila became an outspoken leader of the Union of Miners' Wives, organising mining families for improved conditions and services and struggling against the repressive CIA-backed Barrientos regime.



Domitila Barrios de Chungara.

She survived the brutal 1967 San Juan massacre, where soldiers opened fire on striking miners and their wives and children, in part to head off a rumoured alliance with Che Guevara's guerrillas fighting in the Santa Cruz mountains. In the ensuing repression, she was jailed and tortured, suffering a stillbirth and internal injuries which caused chronic health problems throughout her life.

Hunger strike

In 1978, the hunger strike launched by Domitila and four other miners' wives against the Bánzer government (another US-backed dictatorship) captured the spirit of an entire nation. The strikers demanded freedom for imprisoned mineworkers, amnesty for exiled union leaders, demilitarisation of the mines, and general elections. Thousands of Bolivians joined the strike and, on the 23rd day, the government conceded to the protesters' demands. (Uruguayan writer

Eduardo Galeano recounts the episode dramatically in *Memories of Fire*, his chronicle of Latin American popular history.)

Domitila gained international recognition at the International Women's Forum in Mexico in 1975, giving voice to the Bolivian mineworkers' struggle and the critical role of women activists. *Let Me Speak*, her autobiographical account of everyday struggles as a mother, worker, union leader, and political activist, was published in 1978 and has been translated into dozens of languages. In 2005, she was nominated for the Nobel Peace Prize on a slate of '1000 women for peace'.

Domitila was in exile for several years, returning to Bolivia in 1982 – just ahead of the massive neoliberal structural readjustment that closed the state-owned mines where she spent her formative years, and threw 30,000 miners out of work. In her last years, she focused her energies on developing a Mobile School for Political Training, bringing political conscious-



Domitila (far left) led a hunger strike in 1978 that brought down the dictatorship of General Hugo Bánzer.

ness and popular history to new generations in Cochabamba's most impoverished barrios – populated largely by the families of ex-miners – and to communities throughout Bolivia.

Independent spirit

I was privileged to meet Domitila on two visits to Bolivia, in 2006 and 2008. She was a great story-teller, captivating us with anecdotes of modern Bolivian history from her unique perspective as a participant in the events, and conveying immense dignity, compassion, and determination along with her insights. Three hours later and only up to 1985, we almost missed our flight to La Paz.

As the Cochabamba daily *Los Tiempos* editorialises, Domitila was controversial in death as in life. Her independence and critical spirit caused discomfort for some, as much as it offered inspiration to others. She died in poverty with a reduced pension and no medical insurance, aided by the solidarity of friends and comrades including some ex-MAS government officials.

I was reminded of how, on our official visit to the legislative palace in 2006 to hold a press conference demanding Bolivia's withdrawal from the School of the Americas, Domitila was initially refused entry because she had forgotten her identification. Unrecognised by the palace guards, she appeared to them as just another stocky peasant woman without a valid reason to be in the halls of political



Domitila at a protest march in Stockholm in 1980. She gained international recognition for giving voice to the Bolivian mineworkers' struggle and the critical role of women activists.

power.

Domitila's life encapsulates all the possibilities and challenges of Bolivia, demonstrating both the efficacy of collective struggle and the continuing need to confront exploitation, inequality, and entrenched power relationships in government, the workplace, the home, and even within organised popular movements. Her experience reminds us how ordinary people can change the course of his-

tory, a legacy for activists throughout the world. ♦

Emily Achtenberg is an urban planner and a former Research Associate with the North American Congress on Latin America (NACLA) with a focus on Latin American social movements and progressive governments, especially Bolivia. She has published recently in NACLA News, Upside Down World, Bolivia Rising, and Progressive Planning magazine. This article is reproduced from her Rebel Currents blog on the NACLA website (nacla.org/blog/rebel-currents).

Forugh Farrokhzad (1935-1967) was an Iranian poet and film director. Considered by many as one of Iran's most influential female poets of the last century, she is an important, if controversial, figure in the history of modern Iranian poetry.

Let us believe in the beginning of a cold season

Forugh Farrokhzad

And here I am
a lonely woman
at the threshold of a cold season
coming to understand the earth's contamination
and the elemental, sad despair of the sky
and the impotence of these concrete hands.

Time passed,
time passed and the clock chimed four times,
it chimed four times.
Today is the first day of winter,
I know the secret of the seasons
and understand the moments well.
The saviour is asleep in his grave
and earth, the kind acceptor, earth,
invites me to peace.

Perhaps those two young hands were true, those two young hands
buried below the never ending snow
And next year, when spring
sleeps with the sky beyond the window
and shoots thrust from her body
the green shoots of empty branches
will blossom O my dearest one, my dearest only one

Let us believe in the beginning of a cold season

Source: http://members.tripod.com/~Forugh_Farrokhzad/