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The Novartis verdict

The patently wrong priorities of Big Pharma



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Editor's Note

FEW Indian court decisions in recent years have had such widespread ramifications as the country's Supreme Court ruling in April on a patent application by the Swiss-based drug company Novartis. The application, which was for a patent on a cancer drug called Gleevec, had been rejected in 2006 by the Indian patent office. A seven-year battle in the courts ensued, culminating in the Supreme Court decision.

The court's decision to uphold the rejection has been hailed by health activists the world over as a victory for public health. Health activists in the developing world were especially jubilant. To understand why, one has to delve into a little bit of Indian patent history.

Until 2005 Indian patent law did not recognise product patents, which in effect grant a monopoly to the drug manufacturer over the product which it has developed. The law limited patent protection to the process by which the drug was manufactured and this left the door open to other drug companies to attempt to produce the same drug by using a different process. This limitation on patent monopolies proved to be a boon to the development of a local pharmaceutical industry which was free to make generic versions of these drugs using different processes. The result was that India was able to provide not only its own people but also the people of other developing countries with affordable drugs.

But for the big American and European drug multinationals, this breach in their monopoly of the drug market was totally unacceptable. In the trade negotiations in the 1990s leading up to the establishment of the World Trade Organisation (WTO), these corporations not only lobbied their governments to include the issue of patents ('trade-related aspects of intellectual property rights' or TRIPS) on the agenda, but also sought to shape the provisions of the relevant agreement to be adopted by prospective member states of the new organisation. Hence when India acceded to the TRIPS and other agreements as a prerequisite to WTO membership, she was compelled to amend her intellectual property laws to recognise product patents.

However, when this amendment was effected in 2005, a provision was inserted in the amendment, as a result of representations and pressure from health activist groups both locally and internationally, to ensure that patent protection was granted only to genuine inventions. This was intended to stamp out the notorious practice of patenting of known substances – known as 'evergreening' or 'incremental innovation' – by which drug companies could in effect renew the lifespan of their patents beyond the stipulated 20 years by making minor changes, e.g., by claiming patents on new uses of a known substance or on new forms of a known substance such as salts, polymorphs, isomers etc. The relevant section [Section 3(d) of the Indian Patents Act] spells out clearly that to qualify for a patent, such changes must be so significant that they result in 'enhanced

efficacy'. And in the Gleevec case, the Indian Supreme Court made it clear that the criterion for determining efficacy is 'therapeutic' efficacy.

The court clearly found that there was no novelty in Novartis' patent application. Further, it was the failure of Novartis to satisfy the requirement of 'enhanced efficacy' that led the court to uphold the decision of the Indian patent office to reject a patent for Gleevec. The upshot of this is that Indian drug companies will be able to continue producing generic versions of the drug at a fraction of the original price for the benefit of the people of the developing world. The decision also narrows the scope for patenting of known substances.

Novartis, in a bitter response to the decision, charged that it would have a detrimental effect on innovation and the research and development of new drugs. The claim that the Indian decision was contributing to a 'deteriorating innovation environment' is without basis. The court ruled against a patent for Gleevec because there was no evidence of any innovation. By striking a blow against the practice of 'evergreening', the court was providing an impetus to innovation. It was in effect telling the drug companies, 'If you want a patent, then you must innovate!'

And at no time in recent history has innovation in drugs been more vital. For example, the world is now faced with the threat of 'superbugs', i.e., new strains of bacteria which are resistant to antibiotics. This is due to the profligate and immoderate use of antibiotics, and while a global campaign must be mounted to check this abuse, there is a need for new varieties of antibiotics to meet this challenge. The threat has now become so widespread and serious that health authorities are warning of a looming 'catastrophe'. And yet drug companies are reluctant to undertake the necessary research and investment to develop such drugs as they feel more comfortable with raking in more profits by 'evergreening' existing drugs. There are many other situations calling out for pharmaceutical innovation, but this is indeed the most dire. In short, drug companies have to wake up to their social responsibilities.

In our cover story for this issue, we discuss the Novartis judgment and its wide-ranging implications. While explaining why the judgment has been hailed as a landmark one, we focus on the whole issue of patents and how the drug multinationals have been abusing patents to secure monopoly profits. By highlighting the serious problem of the emergence of 'superbugs', we also seek to draw attention to the abject failure of these companies to respond to needs of public health rather than the lure of profits.

— *The Editors*

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The legal challenge by pharmaceutical giant Novartis against the rejection of its patent application in India for a cancer drug – which could have had serious implications for access to affordable medicines – provoked widespread protests within India and abroad. 12

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China's domestic dam plans draw ire at home and abroad

China's dam-building plans, including in one of the country's most seismically active and geologically unstable zones, have raised serious concerns domestically and abroad. *Katy Yan* explains.

CHINA's State Council – the country's ultimate decision-making body – announced its new Energy Development Plan in January, which includes several controversial dams that had previously been suspended as a result of environmental concerns and public opposition.

According to the document posted on the central government's website, hydropower dams on the upper reaches of the Jinsha and Lancang (Upper Mekong), as well as on two of China's last largely free-flowing rivers – the Nu (Salween) and the Yarlung Tsangpo (Brahmaputra) – would be 'kicked off in an orderly manner'.

The announcement took Chinese environmentalists by surprise, and also generated a media frenzy in India, where tens of millions of people depend on the Brahmaputra River, which originates in the Tibetan Plateau.

Li Bo, director of China's oldest environmental group, Friends of Nature, told the *South China Morning Post*: 'There were signs during the past year that mega-dams were staging a comeback after being put on hold for years, but I'm still shocked by the lack of transparency in the decision-making process behind this.'

Nu River back in the spotlight

Among the plans are five contested dams on the Nu River. A total of 13 dams on the Nu were first proposed in 2003 by the local government, which hoped to exploit the region's rich hydropower potential to export electricity to the booming industrial centres on the eastern seaboard. That same year, a new envi-



Large dams on the Lancang River in China have been blamed for disrupting water flows, causing downstream floods when they were opened and droughts when they were closed.

ronmental impact assessment (EIA) law was enacted in China, and the region was inscribed into the Three Parallel Rivers of Yunnan Protected Areas – a UNESCO World Heritage Site that is believed to support more than 25% of the world's and 50% of China's animal species. As a result of public opposition to the dams, Premier Wen Jiabao suspended these plans in 2004.

Since then, the 13 dams have been reduced to five: Songta in Tibet, and Maji, Yabiluo, Liuku and Saige in Yunnan. Together, the dams would displace up to 30,000 people, destroy the Nu River's aquatic ecosystem, and flood the deep scenic gorges for which the Three Parallel Rivers area is known. [UPDATE: Yunnan officials estimate the displacement could be as many as 60,000 people, largely of the ethnic Lisu minority group.]

All five dams are situated in one

of China's most seismically active and geologically unstable zones. Senior geologists in China have repeatedly warned about the risks of seismic activity and extreme climatic events on dam building in the region, including the potential for a domino effect of dam failures should an upstream dam collapse during an earthquake or extreme flood event.

In February 2011, four geologists wrote to the State Council leadership opposing the damming of the Nu River for geological reasons, after dam developers began pushing the five dams again. Their language was blunt: 'The Nu River is on an active fault with frequent earthquakes, and in a landslide-prone area subject to frequent downpours...Due to high seismic and geological risks, large dams should not be built here.'

Despite these warnings, preparatory activity has already begun. Based

on eyewitness accounts, site clearance and road-building at the Songta and Maji dams have started, though no EIAs have been developed. According to a 2012 Ministry of Environmental Protection notice, preparatory works must be included in all hydropower project EIAs.

In addition, while public participation is required under law during the EIA process, this is more rhetoric than reality. Only one EIA has been completed thus far for the Nu River – that of the Liuku Dam – but the full version was never disclosed. Only a summary of the EIA was posted, because the information in the report was deemed a ‘state secret’. Resettlement of an entire village proceeded at the Liuku Dam site despite local objections, and the unsatisfactory process has been well-documented by the Beijing-based group Green Earth Volunteers.

‘[Premier] Wen was able to put those projects on hold for eight years but with his tenure coming to an end, the pro-hydro interest groups are getting an upper hand again,’ said Wang Yongchen, director of Green Earth Volunteers.

Anger abroad

News that China would also be building three dams on the Yarlung Tsangpo/Brahmaputra River sparked immediate concern in India partly because, according to the *Washington Post*, the Indian government learned of the plans through Chinese media reports rather than through diplomatic channels.

The Chinese Foreign Ministry moved quickly to respond by stating that they were in ‘close communication and cooperation’ with India on the issue. According to a Foreign Ministry spokesperson, ‘The construction of the stations will not impact flood control or disaster reduction efforts, or the ecological environment on the lower reaches.’ Both governments have said that they are sharing data on water flow, though no formal water-sharing agreement has been devel-



The five proposed dams on the Nu River (pic) would displace up to 30,000 people, destroy the river’s aquatic ecosystem and flood the deep scenic gorges for which the area is known.

oped that would enable them to assess whether their river is being used fairly and sustainably.

Despite the Foreign Ministry’s assurances, downstream countries continue to criticise China for its lack of transparency. For instance, while China shares the Mekong with five other countries, it has only twice shared water flow data with its downstream neighbours. Large dams on the Lancang (Upper Mekong) River in China have been blamed for disrupting water flows – causing downstream floods when they were opened and droughts when they were closed. Without a transparent process for sharing data on flows and dam operations, such fears and security concerns are likely to increase.

Groups in Burma and Thailand have also expressed concern over the potential cumulative impacts that dams on the Nu (Salween) might have for downstream communities and ecosystems. Thus far, no cumulative impact assessments of dams or analyses of the economic, ecological and cultural benefits that these rivers bring have been completed for either basin.

‘The central problem with hydropower development on the Nu, the Lancang, or any river anywhere, are the additive impacts – environmental, hydrological, seismic – of multiple projects on a single water

course,’ said Dr Ed Grumbine, a US policy expert working in Yunnan who has published extensive research on the topic. ‘Environmental review that assesses only one dam at a time cannot capture the cumulative impacts of multiple dams built in cascades.’

Grumbine adds: ‘China may be undermining its own geopolitical future with downstream countries by not being more cooperative with its plans for dams on transboundary rivers.’

Environmentalists rally to respond

While the State Council announcement makes the dams look like a done deal, Chinese officials have emphasised that at this point, they are just plans. Meanwhile, in response, Chinese and international NGOs are rallying to keep the dams debate in the spotlight. Environmental and resettlement concerns, alternative energy options, and greater transparency will continue to dominate the debate.

China’s new leader Xi Jinping has made repeated promises of greater transparency. These dams will be a key litmus test for whether the government will live up to his words. ♦

Katy Yan is China Programme Coordinator at the non-governmental organisation International Rivers. This article is reproduced from World Rivers Review (March 2013), which is published by International Rivers.

Dealing with the transnational corporations

Threatened by billion-dollar lawsuits arising from investment treaties, several Latin American governments have formed a new grouping to deal with transnational companies.

Martin Khor

LEADERS of several Latin American countries have set up a new coalition to coordinate actions to face the growing number of international legal suits being taken against governments by transnational companies.

A ministerial meeting of 12 countries held in Guayaquil, Ecuador, on 22 April decided on several joint actions to counter the threat posed by these lawsuits, which have claimed millions or even billions of dollars from governments.

'No more should small countries face lawsuits from big companies by themselves,' said Ecuador's Foreign Minister Ricardo Patino at a media conference after the meeting which he chaired. 'We have now decided to deal with the challenges posed by these transnational companies in a coordinated way.'

Seven of the countries, mostly represented by their ministers of foreign affairs, trade or finance, adopted a declaration with an agreement to form a conference of states affected by transnational interests. They are Ecuador, Bolivia, Cuba, Nicaragua, the Dominican Republic, St. Vincent and the Grenadines, and Venezuela.

Representatives of another five countries (Argentina, Guatemala, El Salvador, Honduras and Mexico) also attended the meeting and will convey the results to their governments.

The ministers decided to set up an executive committee, led initially by Ecuador, to coordinate political and legal actions, including sending information on legal disputes involving the states, coordinating joint legal actions and disseminating information to the public.

They also agreed to establish a



Plain packaging laws for cigarettes have been among the subjects of the growing number of international legal suits being taken against governments by transnational companies.

regional arbitration centre for settling investment disputes, based on fair and balanced rules when settling disputes between corporations and states.

The proposed centre is to provide an alternative to existing international tribunals which are seen as biased in favour of investors' interests. The tribunals, such as ICSID (based at the World Bank in Washington), have also been accused of being mired in conflict-of-interest situations. Only a few arbitrators hear a majority of cases, with many of them also appearing as lawyers for companies in other cases, and some being board members of transnational companies.

The ministers also decided to create an 'international observatory' to monitor and analyse investment cases, to reform the present arbitration system, and suggest alternative mechanisms for fair mediation between states and transnational companies.

The observatory would also promote coordination between the judicial systems of Latin American states, to ensure the enforcement of domestic judicial decisions on disputes be-

tween states and transnational corporations. It should also give advice to governments on their negotiations with transnational corporations, especially in trade and investment contracts.

The meeting had been prompted by serious concerns arising from investment cases taken by transnational companies against the governments under bilateral investment treaties and free trade agreements that enable these companies to sue for loss of future profits due, for example, to new government regulations or a cancellation or amendment of a contract.

There have been more than 500 known investor-to-state cases, over 60 alone in 2012. Some countries in the region, such as Argentina, Ecuador, Venezuela and Mexico, have each had 20 to 30 cases taken against them.

The proliferation of cases in recent years has also affected developing countries in other regions, such as South Africa, India, Indonesia and Vietnam, as well as many developed countries.

Disillusionment with the agree-

ments and the arbitration system has prompted a variety of actions by governments such as suspension of negotiations for new treaties, attempts to renegotiate or withdraw from existing treaties, and withdrawal from the jurisdiction of the ICSID tribunal.

The Vice President of Ecuador, Jorge Glas Espinel, briefed the meeting about two arbitration disputes taken against his government by oil companies under bilateral investment treaties (BITs), and on the tribunal judgments which in his view were unfair and even outrageous.

In one of the cases, Ecuador was asked to pay \$2.3 billion compensation (including interest) to the American oil company Oxy, even though the arbitrators recognised that the company had broken the terms of its contract with the government.

Other ministers and officials also presented the experiences of their countries in cases taken against them by foreign investors, and proposed actions that could be taken to avoid future cases or reduce their effects.

A background note explaining the reason for the meeting said that arbitration proceedings and claims by European and US multinational companies against a growing number of states of the South have dramatically increased.

These costly litigations, the majority of which were decided in favour of the investors, not only affect the states' fiscal situation but also pose a serious challenge to their national jurisdiction and sovereignty, and compromise ongoing development plans in Latin America and other regions.

This problem originated in the 1990s when bilateral investment treaties were signed by developing countries in the expectation of attracting foreign investments, but the negative consequences of such commitments have now become evident, said the note.

A second meeting of the newly formed grouping will be held in Caracas in July. ♦

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.

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization: Background and Analysis

The fight against biopiracy and its injustices was the main impetus for the push to have an international treaty to be developed under the Convention on Biological Diversity (CBD). The Convention's third objective of fair and equitable sharing of the benefits from the utilization of genetic resources is itself the result of tough negotiations in the early 1990s when the misappropriation, even theft, of the resources of developing countries and of indigenous peoples and local communities gained international attention. After almost 20 years, when the Convention's broad provisions proved to be inadequate, the Nagoya Protocol on Access and Benefit-sharing was forged in October 2010.

This new legally binding international treaty, however, was born in an atmosphere of controversy when its core content was ultimately decided by a few during the final days of the 10th meeting of the CBD's Conference of Parties in Nagoya, Japan. This book, co-authored by six civil society participants who were actively engaged with the government negotiators and negotiation process, provides a rich account of the background and development of the Protocol. It analyses the main provisions of the Protocol and recommends several actions that can be taken at the national and international levels to ensure that the Protocol objective of fair and equitable benefit-sharing can be delivered with justice restored.

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization

Background and Analysis

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World Bank seeks to eradicate poverty ... by lowering the bar

Some 40 years ago, Robert McNamara, the then President of the World Bank, proposed a 'new strategy' for the Bank to eradicate absolute poverty by the year 2000. The failure to achieve this goal has not dissuaded current President Jim Yong Kim from now proposing a new 'highly ambitious' target for the Bank of eradicating extreme poverty by 2030. In this analysis, *Roberto Bissio* explains why this goal of ending such poverty 'within a generation' smacks of chicanery.

IN a highly publicised speech, World Bank President Jim Yong Kim announced in April that the new 'highly ambitious' target of his institution will be 'ending extreme poverty in the world by 2030'.

This would require three factors: 'an acceleration of the growth rates', 'efforts to enhance inclusiveness and curb inequality' and 'it will require that potential shocks – such as climatic disasters or new food, fuel, or financial crises – be averted or mitigated'.

This would be a 'historic opportunity in front of us', the World Bank President said when making the announcement at Washington's Georgetown University, an institution 'engaged in preparing the leaders of the future'.

Those future leaders were reassured by Kim that 'we are at an auspicious moment in history' and that developing countries have 'a chance – for the first time ever – to end extreme poverty within a generation'.

Historical optimism is healthy, especially when it comes to inspiring youth, but to claim novelty when there is none is like tripping twice over the same stone.

In 1973, 40 years ago, then World Bank President Robert McNamara, former president of Ford Motor Company and former defence secretary to Presidents John Kennedy and Lyndon Johnson, delivered in Nairobi, Kenya, a solemn speech in which he proposed to the Board of Governors of the Bank a 'new strategy'.

The 'ambitious objective' (sic) of McNamara was 'to eradicate absolute



The World Bank's goal of 'poverty eradication in a generation' is less ambitious than it seems.

poverty by the end of this century' (i.e., 2000). This goal was possible, McNamara explained, because 'if the courageous decisions are made, then the pace of development can accelerate'.

Kim adds ethical arguments to his economic analysis: 'Is there anyone here today who would not want to erase this stain from our collective conscience?' McNamara had said the same in 1973: 'Should we not make the moral precept our guide to action? The extremes of privilege and deprivation are simply no longer acceptable.'

Four decades apart, the discourses of Nairobi and Georgetown are very similar. It has been argued that the World Bank will now pay more attention to inequalities, with Kim saying that, because of unequal distribution, 'even if rapid economic

expansion in the developing world continues, this doesn't mean that everyone will automatically benefit from the development process'.

But McNamara had already noticed, in 1973, that 'despite a decade of unprecedented increase in the gross national product [GNP] of the developing countries, the poorest segments of their population have received relatively little benefit [because] rapid growth has been accompanied by greater maldistribution of income in many developing countries'.

Kim argues today that 'ending extreme poverty is not enough. We must also work to boost the incomes of the poorest 40% of the population in each country.' Along the same lines, McNamara said four decades ago that 'the growth of GNP is essentially an index of the welfare of the upper income groups. It is quite insensitive to

what happens to the poorest 40%, who collectively receive only 10-15% of the total national income.'

While 40 years ago the World Bank president criticised as 'shortsighted' the 'politically privileged elites' that 'are rarely enthusiastic' over fighting poverty, the present World Bank chief hails that 'US President Barack Obama and UK Prime Minister David Cameron endorsed the vision of ending extreme poverty globally'.

'I cannot believe,' McNamara had said, 'that the people and governments of the rich nations will turn away in cynicism and indifference'.

The role that the richer nations would not turn away from, was clearly spelled out 40 years ago. McNamara said then: 'If the governments of the developing world – who must measure the risks of reform against the risks of revolution – are prepared to exercise the requisite political will to assault the problem of poverty in the countryside, then the governments of the wealthy nations must display equal courage. They must be prepared to help them by removing discriminatory trade barriers and by substantially expanding Official Development Assistance [ODA].'

Yet, in the following decades, a development-friendly trade system never materialised and ODA never surpassed, in global terms, half the benchmark (also promised in 1973) of 0.7% of the GNP of developed nations.

Thus, Kim presently only promises that poverty eradication is a goal 'which our partners – our 188 member countries – will achieve, with the support of the entire global development community'. But no detail is given as to what developed countries ought to do.

Absolutists vs relativists

Considering the past experience, why is the World Bank now so confident in reaffirming the old promise? When McNamara introduced the concept of 'absolute' poverty, he set the line at 30 cents of a US dollar a day and he emphasised that 'eradicating



Back in 1973, then World Bank President Robert McNamara (pic) had set forth the objective of 'eradicat[ing] absolute poverty by the end of this century'.

poverty means in practice the elimination of malnutrition and illiteracy, the reduction of infant mortality, and the raising of life-expectancy standards to those of the developed nations'.

Adjusted for inflation, those 30 cents would amount to \$1.60 in today's dollars, but the new line is set at \$1.25. And this will certainly not provide education and health, but will only be enough to keep a person from starving, which is the new definition of 'extreme poverty'.

According to the World Bank's own projections, if current growth rates are maintained and inequality does not get worse, there would be a 90% chance of achieving this goal by 2030. The message to the governments of the world is that nothing needs to change to win this war.

Why are the bells not ringing? Where are the fireworks celebrating that humanity is (or will soon be) finally free from want? People are not rejoicing around the world because the poverty measured by the Bank under a fixed line – which does not move as people rise above it – is not the poverty that the public perceives.

'By necessities I understand, not only the commodities which are indispensably necessary for the support of life, but whatever the custom of the country renders it indecent for creditable people, even of the lowest order, to be without....' wrote Adam Smith, the founder of modern economics, in

the 18th century.

Smith included a pair of leather shoes and a linen shirt among those goods that 'the rules of decency' had made essential, even when in ancient times the rich paraded happily in togas and sandals. Smith argued that poverty is relative, but neoclassical economists who proclaim themselves his followers are now supporters of an 'absolute' poverty line.

According to Martin Ravallion, who crunched the poverty estimates of the World Bank for more than a quarter-century, 'those who argue that globalisation is good for the poor tend to be overtly "absolutist"'.

But ordinary people are 'relativistic'. Since 1949, the Gallup Poll has been asking Americans: 'What is the smallest amount of money a family of four needs each week to get along in this community?' The average amount goes up systematically, year after year, in proportion to national income.

That means that if the \$1/day line was correct in 1990, this line should now be located far above \$2, as the world per capita income has more than doubled between 1990 and 2010. Those who live on less than \$2 a day currently number more than half of the world's population. To eradicate this poverty is still possible, because the average global income now equals about \$30 per day per person. But wealth is very unequally distributed, as the Bank already knew decades ago, and to fight against relative poverty does require major changes in societies.

Gordon Fisher, a leading statistical expert from the US Department of Health, has analysed the evolution of the poverty lines in a dozen countries and his conclusion is that they all moved historically in proportion to income.

In 1938, Carroll Daugherty explained that 'a standard budget worked out in the [1890s], for example, would have no place for electric appliances, automobiles, spinach, radios, and many other things which found a place on the 1938 comfort model. The budget of 1950 will undoubtedly make the present one look

as antiquated as the hobble skirt'.

Paradoxically, the advocates of globalisation celebrate the speed of technological change it brings, on the one hand, and, on the other, insist on counting as 'not poor anymore' those who exceed a fixed line of minimum consumption which is less and less in relation to total consumption.

Fisher observes that 'before about 1965, the people who developed (and studied) poverty lines were largely advocates of the disadvantaged rather than theoretical social scientists; they included social workers, employees of state bureaus of labour statistics, labour union representatives, home economists, and employees of federal social agencies, with economists being only one of a number of elements in the mix. However, that situation changed with the beginning of the War on Poverty in 1964. Poverty studies became a distinct field as such, and economists began to get involved in poverty line studies in large numbers. People who had been involved in poverty line studies during the earlier period gradually retired and/or died. As the earlier groups were gradually replaced by economists, it appears that the history and traditions of the earlier groups tended not to be transmitted to the newcomers. As a result, much of the knowledge about the income elasticity of the poverty line was lost to those who are now studying poverty lines.'

Thus, the high-sounding goal of 'poverty eradication in a generation' is only forecasting that by 2030 there will be less than 10% of the global population living under an income that 60 years before (in the 1970s) would have been a bare minimum.

Meanwhile, Christine Lagarde, Managing Director of the International Monetary Fund, the sister institution to the World Bank, seems to align herself with the relativists in this debate, and she announced on 15 May, in a major speech on poverty eradication, that the top 0.5% of the population now holds 35% of the wealth of the world. And inequalities are still rising. ♦

Roberto Bissio is the Executive Director of the Third World Institute based in Uruguay and coordinator of Social Watch. This article is reproduced from the South-North Development Monitor (SUNS, No. 7590, 24 May 2013), which is published by the Third World Network.

Pandemic Preparedness

Creating a Fair and Equitable Influenza Virus and Benefit Sharing System

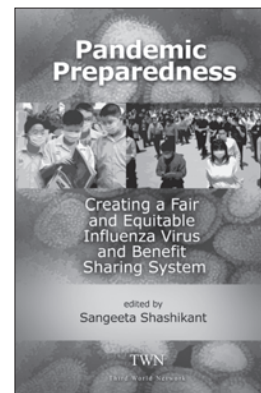
Edited by Sangeeta Shashikant

The WHO, a specialised agency of the United Nations, is mandated to achieve the highest possible level of health for all peoples.

However, in 2007 world attention was focused on WHO when it emerged that WHO's 'Global Influenza Surveillance Network' (GISN) was unfair to the interests and needs of developing countries. This scheme, focused on ensuring that countries shared influenza viruses, failed to deliver fair and equitable benefit sharing, a crucial element to ensure access to vaccines, anti-virals and other technologies at affordable prices to developing countries that were most affected during a severe influenza outbreak of pandemic potential. It also emerged that developed country governments and their entities were winners in the scheme as they profited from the virus sharing system, including by having timely access to vaccines and making IPRs claims over the shared biological materials and products developed using such materials.

Meanwhile, developing countries could face astronomical bills for the purchase of vaccines and other medical supplies, as well as difficulties in accessing such supplies, due to their limited availability. Latest technologies as well as know-how used in vaccine development and production (largely based in developed countries) were also protected by IPRs, creating more obstacles for developing countries that might seek to build their own production capacity.

All these issues came to a head at the 60th WHA in 2007, leading to the adoption of Resolution



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WHA60.28 titled 'Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits'. Negotiations to create a fair and equitable influenza virus and benefit sharing framework in the context of pandemic influenza preparedness are ongoing in WHO.

This book provides an in-depth understanding of the background to, and rationale for, the current WHO negotiations on influenza virus and benefit sharing as well as a front-line view of the negotiations.

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Egypt: Walking the IMF tightrope

The IMF's proposed \$4.8 billion loan could be crucial for restoring Egypt's faltering economy. But implementing the IMF's conditions would be socially and politically costly.

James Maxwell

IN January 1977, a series of riots broke out across Egypt in response to the decision of then president Anwar Sadat to abolish government subsidies for bread and other basic foodstuffs. The riots lasted just two days, but during that time nearly 80 people were killed and hundreds injured in clashes with police and security forces. In this instance, Sadat, already a committed economic liberaliser, was acting under pressure from the World Bank and International Monetary Fund (IMF), from whom Egypt had recently received substantial loans to help deal with its deepening debt crisis.

Today, 36 years later, the conditions for a similar confrontation seem to be brewing in Egypt again. Since the overthrow of Sadat's successor, Hosni Mubarak, in 2011, the state of Egypt's economy has steadily worsened. The official unemployment rate now stands at 13%, inflation is running at 8.3% and, in the last four years, the number of Egyptian households living below the poverty line has increased from 21.6% to 25.2%. Egypt's public finances are similarly weak. Foreign currency reserves have fallen from a relatively secure pre-revolutionary level of \$36 billion to a dangerously low level of \$13.6 billion, the national deficit has reached 8% of GDP, and the trade deficit amounts to more than \$2.5 billion.

Negotiating recovery

Egypt's new government, led by the Muslim Brotherhood's Mohammed Morsi, has been forced to enter into bailout negotiations with the IMF. In March, an IMF delegation travelled to Cairo and offered an initial loan instalment of \$4.8 billion. Should the government eventually accept the money, it will have to agree to a

number of IMF demands, including tax rises, the privatisation of public assets, a reduction of waste and corruption in the public sector and, crucially, the removal of food and fuel subsidies which some estimate account for one-fifth of all state expenditure. [Essam al-Haddad, a leading adviser to Morsi, has since said that Egypt has met all the requirements for the loan, including a phased-out subsidies plan and a sales tax law. – Editor]

This latter demand is particularly contentious given that food prices have soared in recent months as a result of a prolonged fuel shortage, itself a consequence of the burgeoning currency reserve crisis (substantial currency reserve holdings are needed to import oil and gas). The lack of readily available fuel has increased transport costs and forced Egypt's agricultural industry to reduce its production of wheat, making it increasingly difficult for ordinary Egyptians to access necessary resources. These difficulties were compounded in March when the government raised the price of subsidised cooking gas – for the first time in 20 years – as a way, presumably, of signalling its willingness to cooperate with the incoming IMF delegation.

Egypt's Catch-22

Egypt's government has a difficult political balancing act to perform. On the one hand, it is under growing pressure to rescue the economy from a prolonged slump. At a minimum, this will require a targeted programme of capital expenditure, something an IMF loan might be able to facilitate. On the other, as parliamentary elections loom and party political divi-

sions intensify, Morsi and his team will be reluctant to strip back the subsidies which act as an invaluable source of financial support for millions of voters. Any attempts to do so will be met with aggressive and well-organised opposition at the street level.

Opposition exists within Morsi's own movement as well. While Morsi himself is said to be sympathetic to structural economic reform, including reducing or abolishing subsidies, the political wing of the Muslim Brotherhood, the Freedom and Justice Party, is much more reticent, preferring instead to delay reforms until after the current election season has ended or beyond. The split reflects an ongoing debate in Egypt's post-revolutionary politics over whether or not to pursue the Mubarak-era policy of economic liberalisation.

For the moment, Egypt may be able to avoid capitulating to IMF demands. In addition to a \$2 billion interest-free loan from Libya, the ultra-wealthy Gulf emirate of Qatar has offered to purchase \$3 billion worth of Egyptian bonds – and this is on top of an earlier transfer of nearly \$5 billion of Qatari aid to Cairo. But neighbouring Arab states cannot be expected to prop up the Egyptian treasury indefinitely – and most, including Libya, cannot afford to – even if a withdrawal of funds provokes renewed regional instability. Sooner or later, Egypt's government will decide whether to reform the subsidy system and face the potentially explosive political consequences or to reject the IMF bailout cash and risk national bankruptcy. Neither option promises to be anything other than extremely painful. ♦

James Maxwell is a political journalist and regular contributor to The New Statesman online and the Bella Caledonia online magazine. This article is reproduced from ThinkAfricaPress.com.

Field trials

In China's Pearl River Delta, urban planners and advisers are experimenting with new development strategies. The focus is increasingly on the needs of the people, and the authorities are taking people's views into account.



The city of Guangzhou. The development of the Concept Plan for Guangzhou in 2000 marked the birth of strategic urban planning in China.

Christian Wuttke

IN 2011, one in two Chinese lived in an urban area – in 1978, the number was only one in five. Since then, millions of former farmers have moved from the hinterland to the sprawling conurbations on the coast. The policy of reform and opening up that began around 1980 has unleashed what is probably the biggest internal migration in human history.

Government and administration have been largely unable to control or manage the cities' rapid growth. Uncoordinated investment and development projects and informal – even illegal – construction are common in urban China.

Southern China's Guangdong Province was the first region to be opened to market experiments and international investors. In the Pearl River Delta, which cuts through the

middle of the province, the negative side-effects of more than 30 years of rapid development are obvious today. They include an overloaded infrastructure, a shortage of public utilities, environmental pollution and decay in old industrial and residential areas. Little of the once vast and rich agricultural land is left in the Delta.

The Pearl River Delta is an important pioneering region for China's reform policies. The central government has devolved major decision-making powers in economic policy affairs to local administrations, not only to the Delta's Special Economic Zones. Local administrations have much discretion in shaping urban and economic development. As clear-cut responsibilities have not been defined, however, the political and administrative system remains highly complex and opaque, even at the local level.

In China's process of transition, reforms are often confined to clearly

defined territories at first. Local governments initiate many policy innovations in their territory. If they prove effective, their model is copied in other regions or even nationwide. The cities of the Pearl River Delta thus serve as laboratories for national reforms.

At the same time, there is competition among the cities. 'Secrets of success' are not readily shared with others. Competition for international investments, in particular, is becoming more intense. Moreover, there is evidence of coordination problems, especially in regard to shared infrastructure. Transport links within the Delta remain underdeveloped. It adds to the problems that planning is made difficult by the large number of relevant state actors with diverse and often conflicting interests and overlapping powers.

Master and detail plans

Before 1989, there was no legal framework for urban planning. The City Planning Act of that year demands long-term master plans that extend up to 20 years and detailed plans that are normally limited to five years. However, the long-term planning periods and rigid bureaucratic approval processes proved incompatible with the dynamics of fast economic and population growth. In the communist planned economy, land was allocated for different purposes without much regard for real demand.

Today, planning authorities no longer set production targets; they define development goals. The central government no longer allocates resources among state agencies and production units. In principle, urban development should follow municipi-

pal authorities' urban planning. However, special interests of private companies and government agencies often prevail over formal urban planning.

With urban problems getting out of hand and even threatening the cities' competitiveness, however, urban planning has experienced something of a revival in the Pearl River Delta in recent years. Experiments with new planning models began in the late 1990s.

Birth of strategic urban planning

In summer 2000, the Guangzhou Municipal Planning Bureau consulted university planning institutes to draft new strategies. A city-wide vision for Guangzhou in the 21st century was developed without the strict content-specific, formal and methodological stipulations of the City Planning Act. The result was the Concept Plan that was published in the same year. It marked the birth of strategic urban planning in China. The goals defined as 'Expansion in the South, Optimisation in the North, Progress in the East and Connection in the West' back then still apply today:

- 'Expansion in the South' refers to the industrial development of the districts of Panyu and Nansha. An industrial zone is planned – largely for heavy and chemical industry – around a new deep-water port that is currently under construction.
- 'Optimisation in the North' emphasises protection for the city's drinking water resources that are located in that area. However, it also gives scope to more urban growth around the new international airport as well as infrastructure development.
- 'Progress in the East' confirms the role of the Guangzhou Development District as the primary centre of growth in the city. The idea is to attract knowledge-based high-tech industries.
- 'Connection in the West' means improving the transport links be-

tween Guangzhou and neighbouring Foshan.

The aspirations of economic restructuring and urban renewal are huge. Entire districts are being remodelled. The new urban structure is supposed to match well-defined functions, unlike the old structure that evolved in the course of history. To permit flexibility, however, the plans are implemented without detailed stipulations.

Guangzhou wishes to assert its status as the leading political and economic hub of south China. And it has set a precedent: Concept Planning is now practised in every major city in China.

Public participation

In neighbouring Shenzhen, planning has also opened up to new actors – its citizens. Shenzhen was China's first Special Economic Zone and has enjoyed special rights for a long time. The city government still has legislative powers. Thanks to those powers, it was able to introduce statutory planning, which takes the public interest into account and makes formally adopted plans legally binding. Shenzhen has thus tackled the core weaknesses of Chinese urban planning. Specifics include:

- Shenzhen's horizons for statutory plans are considerably shorter; plans are drafted annually.
- Approved plans are publicly announced and legally binding, which serves legal certainty.
- The public is involved in the planning process.

Official planning drafts are made available to the public for inspection for a period of 30 days, so individuals and organisations have an opportunity to submit proposals and ask for modifications. Submissions are examined and approved by an urban planning committee which is organised as an independent authority. It has 29 members, and no more than 14 of them may be officials of the city government. As decisions require a two-thirds majority, however, the officials have a kind of veto power.

As public involvement fell short

of expectations, the municipal government looked for new forms of participation to learn about its people's needs. It set up a company (Public Power) which conducts standardised opinion polls – on the quality of schools, for example, or the state of public transport.

In the meantime, citizens have become more active. Today, they can make proposals via an Internet platform. Urban planning in Shenzhen is certainly not under the democratic control furnished by elections, but the government is serious about inviting citizens to submit proposals. It is keen on an exchange of information.

This 'passive' participation model is evidently deemed a success in China. Public Power, for example, has begun to work on behalf of other regional and municipal authorities in China that need sound foundations for planning.

Outlook

New planning models have not replaced the system of master and detail planning that is legally required in China. They did, however, introduce new supplementary elements that improved effectiveness and functionality substantially. Urban planning is being increasingly professionalised, and its impact on urban development has become stronger. Ever more attention is paid to aspects such as public spaces, image building and competitiveness.

The Pearl River Delta remains a test bed for urban planning and development in China. The authorities in Guangzhou and Shenzhen are proud of their pioneering role. To increase their policymaking capacity, they are trying harder to identify the needs of citizens and businesses. Experiments that work here will – sooner or later – be adopted elsewhere in China. ♦

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A victory for access to medicines

The Indian Supreme Court's 1 April decision which reaffirmed that only medicines that are genuinely new inventions should be granted patents has been hailed as a victory for the rights of patients to have affordable medicines.

Martin Khor

PATIENTS around the world who look to India to supply low-cost medicines to treat their ailments heaved a sigh of relief on 1 April when the Indian Supreme Court turned down a claim for a patent on a cancer drug.

This means that drug companies in India can continue to produce generic versions of the same drug, Glivec or Gleevec, at a much lower price, thus making it affordable to thousands more cancer patients.

Glivec, produced by the Swiss-based company Novartis, can cost a patient up to \$70,000 for a year of treatment, whereas the generic versions of the same medicine made by Indian companies cost around \$2,500. The drug is used to treat some forms of leukaemia as well as a rare type of stomach cancer.

The Supreme Court decision also seems to open the road for patents not to be granted for more medicines, since it confirmed that only drugs that are genuinely a new invention can be granted patents.

Patent monopoly

When a patent is granted to a company for a drug, other companies are not permitted to produce generic versions of the medicine for a period of 20 years or so. The monopoly given to the patent holder enables it to charge high prices since there is a lack of competition. Many or even most patients are unable to buy the medicines, giving rise to frustration and despair especially when their lives are at stake.

Some companies whose patents are about to expire apply for a new patent for the same drug after changing the composition slightly or changing the form of the drug. The 'new'



Novartis' legal challenge against the rejection of its patent application in India had caused anxiety in view of the possible negative implications for access to affordable medicines. Picture shows protesters demonstrating outside Novartis' office in Mumbai.

drug is often not a new invention, but only a minor modification that is made with the aim of having the patent renewed for another period. This practice is popularly termed 'evergreening' of the patent. An extension of the patent term means that the company continues to enjoy the monopoly and high prices, which continue to be out of reach to many patients.

Although governments are obliged under the World Trade Organisation (WTO)'s TRIPS Agreement to have laws allowing for patents to be given for inventions, each country is allowed to set its own definition and standards for what constitutes an invention.

The Novartis case

The Supreme Court decision confirms that the Indian patent authorities exercised their powers lawfully and properly when they rejected the patent application for Glivec on the ground that the medicine was not a new invention.

Novartis had challenged the interpretation given by the Indian patent office to Section 3(d) of the Indian Patents Act that seeks to prevent the grant of patents for non-inventive new forms of known medicines.

The Novartis application had claimed a patent for a new salt form (imatinib mesylate), a medicine for the treatment of chronic myeloid leukaemia, sold under the brand-name Gleevec (or Glivec in other countries).

The Indian patent office had rejected the patent application on the ground that the claimed new form was anticipated in an earlier US patent of 1996 for the compound imatinib and that the new form did not enhance the therapeutic efficacy of the drug. The decision was upheld by the Indian Patents Appellate Board.

The legal challenge from Novartis had caused anxiety among patients' groups, governments of developing countries and some international organisations in view of the possible negative implications for access to affordable medicines if the



While the Novartis-produced Glivec can cost a patient up to \$70,000 for a year of treatment, the generic versions of the same medicine made by Indian companies cost around \$2,500. Picture shows one of the generic versions on sale in an Indian pharmacy.

Novartis petition succeeded.

Most developing countries rely on Indian generic drug companies for the supply of low-priced medicines for many diseases.

A weakening of the interpretation or use of Section 3(d) would have enabled multinational drug companies to extend their patent monopolies based on 'evergreening' or 'trivial' incremental improvements, which could delay the supply of generic medicines for the treatment of HIV/

AIDS, cancer and other diseases.

The decision by the Indian Supreme Court is thus of major significance not only for India but for patients and health authorities in the developing countries.

Balancing patents and public health

In interpreting Section 3(d), the Supreme Court observed that this section was introduced in the 2005

Amendment to the Patents Act to ensure that while India allowed product patents on medicines in accordance with its WTO obligations, it did not compromise public health through 'evergreening' of pharmaceutical patents.

The Court hence took into account the concerns about the impact of the TRIPS Agreement on public health and on the development of an indigenous pharmaceutical industry. Moreover, it considered the implications of the Novartis case for the availability of essential medicines at affordable prices globally.

The Court decision reproduced two letters from Dr Jim Yong Kim, the former Director of the Department of HIV/AIDS at the World Health Organisation (and current President of the World Bank), and from UNAIDS (the Joint UN Programme on HIV/AIDS) to the Indian Health Minister expressing their concerns relating to the continuous availability of affordable Indian generic drugs in other developing countries.

Thus, the Supreme Court decision has implications beyond India. It upholds the high standards by which drug patent applications can be processed. While genuinely new inventions are granted patents, drugs that are not really new need not be.

The implication is that Indian generic companies can be expected to produce many more medicines in future, and continue their reputation as the 'pharmacy of the developing world'.

It is also heartening that the Court decision reaffirms the priority for concerns for the patients' right to receive treatment at more affordable prices.

The decision is also likely to spark interest among other developing countries in the Indian patent law and the policies guiding it. Developing countries can learn from the Indian approach of balancing patents and public health. ♦



Medicines being produced at the manufacturing facility of a generic drug company near Mumbai. Most developing countries rely on Indian generics producers for the supply of low-priced medicines.

The larger implications of the Novartis-Glivec judgment

The Indian Supreme Court judgment on the Novartis-Glivec case is remarkable because it has gone beyond the specific technical and legal issues surrounding patents and has put the matter in a much larger political and economic perspective. What the judgment says and what it implies has tremendous significance for the patent regimes in developing countries beyond the secondary patenting issues.

Sudip Chaudhuri

THE Supreme Court of India has recently rejected the plea of Novartis for patent protection for its anti-cancer drug sold in the name of Glivec or Gleevec. The judgment has evoked extreme reactions. While some have greeted it as a landmark judgment which will make medicines more affordable, others have condemned it as harmful for innovation and foreign investment. We will analyse here some of the implications of the judgment.

Patent laws are national laws. With no restrictions before the introduction of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation in 1995, India abolished product patent protection in drugs (and food) in 1972. Even under TRIPS, though product patents are mandatory, countries have some flexibilities to frame their own patent laws to suit their national interests. Thus legally and legitimately, what is patentable in India may not be so in other countries, as we will see below.

Why the patent was rejected

Novartis applied for a patent for imatinib (and other derivatives of a compound) in the United States in April 1994, abandoning an earlier application made a year earlier. (The judgment refers to this as the Zimmermann patent after the name of the inventor.) After getting marketing approval, what the company started selling as the drug for treating chronic

myeloid leukaemia was not imatinib but a derivative of it, viz, imatinib mesylate. It did not apply for a separate patent for imatinib mesylate in the US because, as the judgment shows, the Zimmermann patent covered not only imatinib but also imatinib mesylate.

Novartis could not at that time apply for a patent for imatinib/mesylate in India because the country was not required to provide protection for a patent applied or granted elsewhere before TRIPS came into being, i.e., before 1 January 1995. What it did in India after 1995 (in July 1998) was to apply for a patent for the beta crystalline form of imatinib mesylate. But what India did in 2005 when she reintroduced product patent protection was to insert a condition in Section 3(d) of the Patents Act that 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance' is not patentable.

Under the transitional arrangements used by India as permitted by TRIPS, the Novartis beta crystalline patent application was processed for grant of patent only after 2004. The patent was rejected initially by the patent office in January 2006 and then by the Intellectual Property Appellate Board (IPAB) in June 2009. The Supreme Court judgment is basically related to the appeal of Novartis against this rejection of the patent by the IPAB.

Novartis argued before the Su-



Novartis' corporate headquarters in Basel, Switzerland. The Indian Supreme Court held that Novartis could not demonstrate enhanced therapeutic efficacy of the new form of its cancer drug.

preme Court that starting from the Zimmermann patent, the beta crystalline form for which the patent was applied in India was developed through two inventions – from imatinib to imatinib mesylate and then from the latter to the beta crystalline form. The Supreme Court however ruled that imatinib mesylate was a known substance directly following from the Zimmermann patent and hence does not qualify as an 'invention' in terms of clauses (j) and (ja) of Section 2(1) of the Patents Act. It also ruled that the beta crystalline form does not satisfy the Section 3(d) criterion. The Supreme Court interpreted the word 'efficacy' to mean therapeutic efficacy. The Supreme Court held that 'therapeutic efficacy of a medicine must be judged strictly and narrowly'. Improved therapeutic efficacy must be claimed and established. The Supreme Court rejected the appeal and hence denied the patent to Novartis because Novartis could not demonstrate that the new form (beta crystal-

cc Andrew Hecht

line) of the known substance (imatinib mesylate) enhanced the therapeutic efficacy of the drug. The court rejected Novartis' claims of better bioavailability and better physical characteristics such as better storability of the compound, saying that these do not necessarily improve the therapeutic effect.

When Novartis applied for a patent for the beta crystalline form in India in 1998, it did not claim any therapeutic benefit. It was not required to do so at that stage because the Section 3(d) efficacy criterion was introduced much later. After the patent was taken up for examination after 2004 and after the grant of the patent was opposed (India's legislation provides for pre-grant opposition), Novartis filed affidavits to satisfy the requirement of Section 3(d). But it was admitted that no study had been done earlier since nowhere in the world had such conditions been imposed. Acknowledging the spirit of the law, Novartis had the honourable option to withdraw the patent application. Rather what it did was to wage a seven-year-long legal battle not only opposing the rulings of the patent office and the appellate board but also filing writ petitions for declaring Section 3(d) as unconstitutional! (The latter was dismissed by the Madras High Court in 2007.)

Noting that what Novartis was selling in the US and in India was imatinib mesylate and not the beta crystalline form, the court remarked that the case of Novartis 'appears in rather poor light and the claim for patent for beta crystalline form of imatinib mesylate would only appear as an attempt to obtain patent for imatinib mesylate, which would otherwise not be permissible in this country'.

The implications

The judgment will have a positive impact on affordability and accessibility of medicines. Generic companies sell the anti-cancer drug at a fraction of the more than Rs100,000 charged by Novartis for a dose of the product. A patent is given

for a limited time period, currently for 20 years under TRIPS. Thus after the expiry of the patent, other firms can and do enter the market and that results in a fall in the prices and hence profits of the patent holder. The multinational corporations (MNCs) holding the patents often try to block or delay this competition by getting secondary patents on minor changes to the product, a practice which has come to be known as evergreening. But the objective of the patent system is not to encourage or permit patenting of new forms of old drugs to basically extend the patent term. Thus what, basically, the Supreme Court in interpreting Section 3(d) is saying is that consumers should not be forced to pay higher prices just because it is chemically a new drug unless there is a therapeutic benefit involved. It is not saying that a new form cannot be patented. All that it is saying is that under the current law it cannot be patented unless it is therapeutically more effective.

It will be more difficult to indulge in evergreening in India. Considering the strict criterion of efficacy, patenting new forms of non-patented drugs or patent-expired drugs will not be easy. The patent office in India is unlikely to grant such patents unless therapeutic efficacy is demonstrated. And demonstrating that new forms are therapeutically more effective may not be that easy, as the Novartis case suggests. Thus some medicines which otherwise would have been patented with high monopoly prices will not be patentable and hence will be more affordable. It must be added however that the Supreme Court here did not define the scope of therapeutic efficacy – it was not necessary in the Novartis case since Novartis could not demonstrate any improvement whatsoever. But Section 3(d) provides the explanation that salts, esters and other derivatives of known substances will be considered to be the same substance, 'unless they differ significantly in properties with regard to efficacy'. Supposing in future a new form shows some increase in efficacy. How does one interpret the word 'significantly' in this case? These ques-

tions are still open.

In the name of innovation, mindless patenting goes on in countries such as the US – a model which many developing countries willingly or not so willingly follow – much against the interests of the consumers. Linking patenting to therapeutic benefit is a simple but powerful idea. The Supreme Court decision is consistent with TRIPS and has been arrived at not arbitrarily but by following transparent and internationally accepted legal processes. Thus other countries which have stricter patent regimes might be induced to introduce similar provisions in their patent laws to make drugs more affordable. Thus the judgment has significant international implications as well.

Compulsory licensing

But new drugs which are currently under patents or those that will be patented in future will continue to be under monopoly till the patents expire. It is important to note that if rather than in April 1994, Novartis had filed the patent in the US a few months later – after 1 January 1995 when TRIPS came into effect – the anti-cancer drug would have been eligible for a patent in India as a new substance and Section 3(d) would not have been applicable (till that patent expired). Thus Section 3(d) deals with only a part of the problem. Another important flexibility which TRIPS permits under certain conditions is compulsory licensing. A beginning has been made with the grant of a compulsory licence to Natco, an Indian generic company, for another anti-cancer drug, sorafenib tosylate (sold as Nexavar by the patentee, Bayer). Affordability of patented medicines will depend to a large extent on how the compulsory licensing system evolves in India.

India suffers from the twin problems of high prices of patented medicines and low access to generics, i.e., non-patented medicines. Due to a variety of factors including poor public health facilities, and inadequate insurance facilities, drug access is very low in India. Indian generic companies,

especially the larger ones, are increasingly selling in the foreign markets, particularly the more lucrative Western markets, rather than in the domestic market. Price control of medicines is a major issue in India. Thus to ensure proper healthcare much more needs to be done in India. But to say that non-patent factors are also important does not mean that patent factors are not important. It is undeniable that the Indian generic industry has made patented drugs more affordable both in India and abroad.

The larger significance

What is remarkable about the judgment is that it has gone beyond the specific technical and legal issues surrounding the patent dispute and has put the matter in a much larger political and economic perspective. What the judgment says and what it implies has tremendous significance for the patent regimes in developing countries beyond the secondary patenting issues relating to Section 3(d). ‘In order to understand what the law really is, it is essential to know the “why” and “how” of the law. Why the law is what it is and how it came to its present form?’ After independence, India continued with the product patent system. Why did she abolish product patents in pharmaceuticals in 1972? Why did she reintroduce it in 1995? What was the impact of the different patent regimes? It went into the history of the patent law of the country and the experience under different patent regimes.

Based primarily on the Bakshi Tek Chand Committee Report (1950), the Ayyangar Committee Report (1959) and Chaudhuri (2005) (the text of the judgment can be accessed from <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>), the judgment noted that before 1972 the country did not benefit – product patents did not promote innovation and industrial activity but the people had to pay high monopoly prices. But after 1972 when product patents were abolished, not only did the industry develop but prices also became more affordable. In the light of such a posi-

tive past experience, the judgment also highlighted the concerns expressed about the negative impact of reintroduction of product patents in line with TRIPS.

Thus the judges felt that the old debate about the role of product patents is still relevant. The principal economic rationale for granting patents is that it will stimulate investment for research for innovation. This is the positive effect. But, patent rights, which exclude others from producing and marketing the product, lead to inhibition of competition and hence high prices and less access. This is the negative effect. As the judgment specifically mentions, it is important to balance these diverse effects. Where innovation is absent or trivial or limited, a country is justified in denying a patent because the negative effect is stronger than the positive effect. In earlier stages of development when countries are net users, not net developers, of R&D-intensive products, they lose by granting product patents. Thus, most developed countries including Switzerland (where Novartis is located) adopted pharmaceutical product patenting only after they reached a higher degree of economic development with innovative capabilities.

Novartis says that the Supreme Court decision will destroy the incentive to do R&D and to invest in the country. It also says that it will be cautious before introducing new drugs in the country. If Novartis does not introduce new drugs in the country, that would be a good ground for issuing a compulsory licence. The denial of the Glivec patent will, of course, have an adverse impact on their profits. But India accounts for a very small part of their global market and profits. Hence any such fall from their operations in India is unlikely to have any significant impact on the funds for R&D and hence the incentive to do new drug R&D. (Incidentally the same is true for some Indian companies such as Dr Reddy’s and Glenmark which have started new drug R&D – their main target is the large and lucrative patent-protected Western markets.) As far as Novartis

is concerned, what needs to be considered in India is what they have done in India. It is here that the historical perspective provided by the judgment becomes so relevant. Ciba-Geigy and Sandoz (the companies which later merged to form Novartis) and other MNCs enjoyed full product patent protection in India before 1972 but were not involved in innovative activities. They were also not even keen to undertake investments for manufacturing from basic stages so as to develop the industry in the country. Now that product patents have been introduced in India, what are the MNCs doing? As I have discussed in Chaudhuri (2012), they are again more keen on importing patented products and selling at high prices rather than innovating or manufacturing in the country.

The deeper implication of the judgment is that it is not only justified to deny patents when incremental innovation is trivial, as in the case of the beta crystalline patent application. The judgment has linked the entire question of patenting with net benefits to society and has highlighted the relevance of specific conditions of a country for deciding the appropriate patent regime. If, as the judgment notes, the experience in the 1950s and 1960s justified a change in the patent regime in the 1970s, then should not a similar experience after 2005 lead to another change? Of course in the 1970s India had the freedom. Now countries are bound by TRIPS. But TRIPS is not a permanent agreement. It provides for review. The Supreme Court did not comment on the fairness or otherwise of TRIPS. But what it says and implies does provide a justification for a review of TRIPS. ♦

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What should we learn from the Novartis judgment?

In the following piece, *KM Gopakumar* traces the legal background to the Indian Supreme Court decision on Novartis' claim for a patent and explains the significance of some aspects of the judgment.

ON 1 April the Supreme Court of India delivered a landmark judgment in which the Court upheld the decision of the Indian Patent Office to reject Novartis's patent application on imatinib mesylate, a life-saving medicine used for the treatment of chronic myeloid leukaemia (CML). The judgment put an end to a series of litigations between Novartis, generic drug companies and the Cancer Patient Aid Association (CPAA).

Novartis had obtained the marketing approval from the US Food and Drug Administration (USFDA) in 2001 for the treatment of CML. It started marketing the medicine under two brandnames, Gleevec or Glivec. In India Novartis started marketing the medicine in 2002 at a price that would entail an expenditure of \$2,500 per person per month. However, during the same year Natco, an Indian generic company, started marketing the generic version of imatinib mesylate at less than a tenth of the originator's price. This move by Natco prompted another five generic companies to develop the generic version of imatinib mesylate. The Supreme Court decision now ensures the supply of imatinib mesylate from the generic companies within a price range of \$100-150 per month.

Apart from ensuring an uninterrupted supply of the generic version of imatinib mesylate, the decision of the Court is an eye-opener for everyone regarding the greedy practices of multinational pharmaceutical corporations, which put profits above people's health. Further, it underlines the



Novartis has recovered far more than the tiny investment it made in R&D for imatinib mesylate, which it markets under the brandnames Glivec and Gleevec.

importance of curbing the patenting of a known substance by using the existing flexibilities in the World Trade Organisation (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The history of imatinib mesylate

Imatinib mesylate represents a new pathway in cancer treatment known as targeted therapies. Generally speaking, the treatment targets the affected cells without harming other cells. Imatinib mesylate targets the activity of a protein known as BCR-ABL which leads to CML. The basic research which led to the identification of the protein goes back to the early 1960s. However, it was a team of researchers led by Dr Brian Druker which developed the drug.

According to Druker, the entire research was primarily driven to meet the needs of CML patients and he had to lobby Novartis to invest money in the development of imatinib mesylate. He writes: 'I was caring for patients in my clinic with CML who had no treatment options remaining. I be-

came their voice, lobbying my remaining contacts at Novartis ... to move this project forward. Ultimately, we prevailed.'

This polite statement by Druker is confirmed by Dr Arnold S Relman writing in the *Journal of the American Medical Association*: 'Novartis was not "the innovative force". Not only was all the basic research done in academic institutions, but so were the initial clinical investigations

that showed [the compound] STI 571 to be specifically effective against CML cells in vitro and in vivo. In fact, it took a few years for Brian Druker, the investigator most responsible for these latter studies, to convince Novartis that it should invest in a crash programme to develop Gleevec and to undertake large-scale clinical trials.'

James Love of the NGO Knowledge Ecology International points out that the cost incurred by Novartis for the research and development (R&D) of imatinib mesylate is not very high. He cites the following facts to show the low expenses for the development of imatinib mesylate compared to the R&D cost of other medicines. According to Love, imatinib mesylate is designated as an orphan drug and this makes Novartis eligible for a tax credit to defray 50% of costs of clinical trials. Further, the approval letter for imatinib mesylate shows that the number of patients enrolled for the clinical trials was only 1,027, against the normal average of 2,667 for other medicines. Imatinib mesylate also obtained an accelerated approval in almost three years compared to 5-7

years in the case of other medicines. The clinical trial was started in June 1998 and the USFDA provided the marketing approval on 20 May 2001.

However, after the marketing approval Novartis abused its patent monopoly and sold the medicine at an exorbitant rate. The sales turnover of imatinib mesylate in 2012 was around \$4.68 billion. Novartis has recovered far more than the tiny investment it made in R&D for imatinib mesylate.

Novartis used different strategies to maintain the abuse of monopoly. It filed patents for the beta crystalline form of imatinib mesylate in many developing countries and sued generic companies. It financed patients groups to sue the government of Argentina to include imatinib mesylate as part of the state healthcare programme. In South Korea Novartis used political pressure to prevent the issuance of a compulsory licence on imatinib mesylate. To ease the criticism of the high prices, Novartis introduced a patient assistance programme known as the Glivec International Patient Assistance Programme (GIPAP). However, Dr Purvish Parekh of the Tata Cancer Hospital in Mumbai, India, filed an affidavit in 2007 with the High Court of Madras stating that Novartis misused GIPAP for post-marketing surveillance and further clinical trials.

Disappointed with the excessive price, Druker wrote in 2007: 'The price at which imatinib has been offered for sale by Novartis around the world has caused me considerable discomfort. Pharmaceutical companies that have invested in the development of medicines should achieve a return on their investments. But this does not mean the abuse of these exclusive rights by excessive prices and seeking patents over minor changes to extend monopoly prices. This goes against the spirit of the patent system and is not justified given the vital investments made by the public sector over decades that make the discovery of these medicines possible.'

The litigation

The litigation on imatinib mesylate started in 2003 in India. It

took almost 10 years before a final answer was obtained from the Supreme Court, the highest judicial authority in India. Theoretically speaking, Novartis can file a review petition at the Supreme Court but legal experts believe there is little chance of overturning the present decision.

After obtaining marketing approval for imatinib mesylate in India in 2002, Novartis applied for exclusive marketing right (EMR) in the country. Under the TRIPS Agreement, a developing country using the transition period for the introduction of a product patent regime should accept product patent applications during the transition period through what is known as the 'mailbox' facility. It should also provide EMR as an interim arrangement till the introduction of the product patent regime. The EMR will be granted on satisfaction of two conditions: first, patent protection and marketing approval in a foreign country, and, second, marketing approval in the country where the mailbox application is filed. After the introduction of product patent protection, the application would be examined as per the patentability criteria. Novartis obtained EMR in November 2003 for imatinib mesylate.

Novartis's EMR was challenged by Natco at the Delhi High Court primarily on the ground that imatinib mesylate was invented prior to 1995 and therefore not eligible for EMR under the Indian law. The Indian Patents Act clearly mentioned that EMR should be given only to those inventions claiming identical article or substance in a convention country on or after 1 January 1995. According to Natco, the invention mentioned in the 1998 application filed in India had already been disclosed through another patent application filed in the US in 1994, known as the Zimmermann patent. While Natco's writ petition was pending in the Delhi High Court, Novartis approached the Mumbai High Court seeking injunctions against Natco and its distributors to prevent the marketing of the generic version of imatinib mesylate. These litigations became redundant in 2005 due to the amendment of the Patents

Act to introduce product patent protection.

Using the pre-grant opposition provision of the Patents Act, generic companies including Natco and CPAA challenged the patent application of Novartis on imatinib mesylate. In January 2006 the Patent Office rejected the application, citing the absence of novelty and industrial application and the newly amended Section 3(d) of the Patents Act, which is supposed to curb the patenting of known substances.

Novartis challenged the decision of the Patent Office at the Madras High Court. It also challenged the constitutional validity of Section 3(d) and the compliance of the provision with the TRIPS Agreement through two writ petitions. Eventually the petition challenging the decision of the Patent Office was transferred to the Intellectual Property Appellate Board (IPAB). The Madras High Court heard and rejected the other two petitions. Novartis decided not to appeal against the decision of the Madras High Court.

The IPAB also rejected the patent application of Novartis but only on the ground of Section 3(d) of the Patents Act, and held that the application satisfied novelty and eligibility criteria under the Patents Act. Novartis approached the Supreme Court against this decision. At the same time Natco and CPAA also approached the Supreme Court challenging the findings of the IPAB, which rejected the findings of the Patent Office on lack of novelty and inventive step in Novartis's patent application.

The Supreme Court on Novartis's greed

There were thus two questions which came up before the Supreme Court. The first concerned the legal validity of the IPAB decision which rejected Novartis's claim for patent protection on the beta crystalline form of imatinib mesylate under Section 3(d) of the Patents Act. The IPAB accepted Novartis's claim on novelty and inventive step but rejected the

patent under Section 3(d). According to Section 3(d), a patent on a known substance cannot be granted unless there is a significant enhancement in the known efficacy. Further, as per the explanation of Section 3(d), 'salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.'

The second question which the Supreme Court had to consider was Natco's and CPAA's legal challenges on the IPAB's decision to accept the argument of Novartis with regard to novelty and inventive step on the beta crystalline form of imatinib mesylate. As mentioned above, Novartis could not rely on the patent application filed in developed countries in 1994 known as the Zimmermann patent, because there was no product patent protection in India at this time and the TRIPS Agreement only came into force in 1995. However, realising the market potential, it filed a patent application in India in 1998 seeking priority from a patent application filed in 1997 in Switzerland. Natco and CPAA argued that the invention claimed in the 1998 application, i.e., the beta crystalline form of imatinib mesylate, was fully disclosed in the 1994 patent application. Further, making a beta crystalline form of salt from the imatinib molecule is obvious to a person skilled in the art and therefore does not satisfy the requirement of inventive step. Even though the Patent Office had accepted these arguments, the IPAB rejected them and denied Novartis's application only on one ground under Section 3(d).

At the Supreme Court, Novartis came up with a brand new argument which was not mentioned in its patent application filed in 1998. Novartis argued that the invention mentioned in the 1994 patent application was only the imatinib freebase and that two more inventive steps were required to reach the beta crystalline form of imatinib mesylate. The first inventive step was the development

of salt from imatinib freebases and the salt was known as imatinib mesylate. The second inventive step was the development of the beta crystalline form of imatinib mesylate from imatinib mesylate. According to Novartis, the Zimmermann patent did not disclose these two inventive steps and therefore did not cover the beta crystalline form of imatinib mesylate claimed in its 1998 patent application.

On the issue of whether imatinib mesylate, i.e., the salt form, is disclosed in the Zimmermann patent, the Court clearly brought out the evidence to show that the Zimmermann patent covers not only the imatinib freebase but also the salt form of imatinib. Towards this purpose the Court found the following points.

The Court found the following statement in the Zimmermann patent, which clearly covers both freebase and salt of imatinib: 'Owing to the close relationship between the novel compounds in free form and in the form of their salts, including those salts that can be used as intermediates, for example in the purification of the novel compounds or for the identification thereof, hereinbefore and hereinafter any reference to the free compounds should be understood as including the corresponding salts, where appropriate and expedient.'

The Court further found that Novartis filed the patent application for the beta crystalline form of imatinib mesylate in the US on 18 January 2000. The US patent was granted only after five and a half years, on 17 May 2005, following an order of the US Appellate Court dated 23 November 2003. The US Patent and Trademark Office (USPTO) had initially refused the patent application. The Court found out that Novartis launched the medicine in the market much earlier on the basis of the Zimmermann patent and declared to the USFDA that the Zimmermann patent covers 'the composition, formulation, and/or method of use of imatinib mesylate'.

Further, the Court also found that Novartis applied for extension of the term of the Zimmermann patent immediately after obtaining the market

approval for imatinib mesylate. According to the Court, 'this application leaves no room for doubt that imatinib mesylate, marketed under the name Gleevec, was submitted for drug approval as covered by the Zimmermann patent'.

The Court also cited the fact that Novartis successfully prevented Natco from marketing its generic version of imatinib mesylate in the UK on the basis of the Zimmermann patent. The Court quoted from the US Board of Patent Appeals decision rejecting the USPTO order of refusing a patent for the beta crystalline form of imatinib mesylate. The Board of Appeals allowed the patent claim on the beta crystalline form but stated: 'In claim 23, Zimmermann recites imatinib, a specific compound within the scope of formula I, or a pharmaceutically acceptable salt thereof. In light of 35 U.S.C. § 282, therefore, we may presume that the specification of the Zimmermann patent teaches any person skilled in the art how to use imatinib, or a pharmaceutically acceptable salt thereof, in a pharmaceutical composition for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease.'

Therefore the Court clearly stated: 'That imatinib mesylate is fully part of the Zimmermann patent is also borne out from another circumstance. It may be noted that after the Zimmermann patent, the appellant applied for, and in several cases obtained, patent in the US not only for the beta and alpha crystalline forms of imatinib mesylate, but also for imatinib in a number of different forms. The appellant, however, never asked for any patent for imatinib mesylate in non-crystalline form, for the simple reason that it had always maintained that imatinib mesylate is fully a part of the Zimmermann patent and does not call for any separate patent.'

To support its argument regarding the non-coverage of the beta crystalline form of imatinib mesylate in the Zimmermann patent, Novartis argued that there is a difference between

coverage and disclosure in a patent application. According to Novartis, the coverage of a patent application is different from the scope of disclosure of the patent. In simple terms it means that the absence of novelty or inventive steps can be attributed to the steps involved in making the beta crystalline form of imatinib mesylate only if there is a complete disclosure in the Zimmermann patent.

While rejecting that argument the Court said: 'The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the coverage in a patent might go much beyond the disclosure thus seems to negate the fundamental rule underlying the grant of patents.'

The Court further stated: 'We would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skilful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent.'

The Court did not examine whether transforming imatinib mesylate into the beta crystalline form of imatinib mesylate satisfies the inventive-step criterion. According to the Court, there was no need to examine that because the beta crystalline form of imatinib mesylate is a polymorph and directly attracts Section 3(d) of the Patents Act, which

checks the patenting of known substances.

Novartis also made two arguments before the Court against the application of Section 3(d) to evaluate its patent application on the beta crystalline form of imatinib mesylate. Firstly, Novartis argued that Section 3(d) is a provision of abundant caution and does not apply to inventions which satisfy basic patentability criteria of novelty, inventive step and industrial application. Secondly, Novartis argued that since there was no known efficacy of imatinib freebase and imatinib mesylate, it is not possible to show that the beta crystalline form of imatinib has any enhanced efficacy.

The Court rejected both the arguments.

The Court clearly stated that the legislative intention shows very clearly that 'in course of the Parliamentary debates, the amendment in section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds'.

On the second argument, the Court decided: 'On facts also we are unable to accept that imatinib mesylate or even imatinib was not a known substance with known efficacy. It is seen above that imatinib mesylate was a known substance from the Zimmermann patent. In the NDA [New Drug Application] submitted by the appellant before the US FDA, it was clearly stated that the drug had undergone extensive preclinical, technical and clinical research.' Therefore the Court rejected the claim that the

efficacy of imatinib mesylate or even imatinib is unknown.

Therefore on the question of the Section 3(d) test, the Court said 'it must be held that on the basis of the materials brought before this Court, the subject product, that is, the beta crystalline form of imatinib mesylate, fails the test of section 3(d), too, of the Act. We have held that the subject product, the beta crystalline form of imatinib mesylate, does not qualify the test of Section 3(d)'.

The Court also noted the fact that on the package the description of the drug includes 'each film coated tablet contains: 100 mg Imatinib (as Mesylate)' and there was no reference to the beta crystalline form of imatinib mesylate.

On the argument that there are two steps involved to develop the beta crystalline form of imatinib mesylate from the imatinib freebase, the Court remarked that 'this position is not reflected in the subject application, in which all the references are only to imatinib in free base form (or to the alpha crystalline form of imatinib mesylate in respect of flow properties, thermodynamic stability and lower hygroscopicity)'.

On the patent application on the beta crystalline form of imatinib mesylate, the Court observed: 'It may also be stated here that while going through the Zimmermann patent one cannot but feel that it relates to some very serious, important and valuable researches. The subject patent application, on the other hand, appears to be a loosely assembled, cut-and-paste job, drawing heavily upon the Zimmermann patent.'

Implications on the patenting of known substances

The most important outcome of the Court decision is its implication on the future of patenting of known substances. It is a well-known fact that multinational pharmaceutical corporations obtain multiple patents on the same molecule. Multiple patenting of known substances can delay the entry of generics and prevent competition in the pharmaceutical market.

The Court clearly recognised the policy concern with regard to patenting of known substances as reflected in Section 3(d) of the Indian Patents Act. Towards this end, it traced the legislative history of the Act, including the parliamentary debate over the 2005 amendment which introduced Section 3(d). The Court noted: 'In course of the debate in Parliament, an amendment (by way of addition) in clause (d) of section 3 was proposed by the Government in order to allay the fears of the members from the Opposition concerning the introduction of product patents for pharmaceuticals and agricultural chemicals, and it was on the Government's assurance that the proposed amendment in section 3(d) (besides some other changes in the Act) would take care of the apprehensions about the abuse of product patent in medicines and agricultural chemical substances that the Bill was passed by Parliament.'

Section 3(d) states that the following is not an invention within the meaning of the Patents Act: 'The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.'

One important critique of Section 3(d) is over the lack of explanation with regard to the word 'efficacy'. In the absence of a definition, the term 'efficacy' may lead to multiple interpretations. It can mean technological efficacy, therapeutic efficacy, economic efficacy or efficacy in the physical property of the substance.

The Court agreed with the Ma-

dras High Court's interpretation of the term and held that: '... the explanation requires the derivative to "differ significantly in properties with regard to efficacy"'. What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy.'

Thus the Court clearly narrowed down the meaning of the term 'efficacy' to therapeutic efficacy. Further, the Court clearly stated that any improvement in the physical property does not pass the scrutiny of Section 3(d). The Court stated: 'While dealing with the explanation it must also be kept in mind that each of the different forms mentioned in the explanation have some properties inherent to that form, e.g., solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of "invention". Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy.'

However, the Court did not examine what the requirements to prove enhancement in therapeutic efficacy are. It did not look into questions like whether increased bioavailability or less side-effect can be considered as an enhancement of therapeutic efficacy. These questions may be litigated in future. Hence, the decision on Novartis is a landmark decision but not the final decision.

Thus the Court further refined the application of Section 3(d) to curb the patenting of known substances. As mentioned above, the Court did not answer whether the beta crystalline form of imatinib mesylate satisfies the inventive-step criterion, i.e., whether the making of the beta crystalline form from the imatinib freebase or imatinib mesylate is obvious to a person skilled in the art. It made a passing reference that 'whether or not it

involves an "inventive step" is another matter, and there is no need to go into that aspect of the matter now'. Such an examination by the Court could have resulted in much greater narrowing down of the patenting of known substances.

There is no doubt that the Novartis judgment is a landmark decision to further the resistance against abuse of patent monopolies in general and the efforts of developing countries to use the flexibilities in the TRIPS Agreement. The moot question is whether developing countries should replicate Section 3(d) in their patent legislation to check the patenting of known substances.

The main shortcoming of Section 3(d) is that it does not shut the door to patenting of known substances and it allows the patenting of known substances on a case-by-case basis if the patent applicant can prove that the claimed invention differs significantly in properties with regard to efficacy. In other words, Section 3(d) does not exclude the patenting of known substances per se and only limits it, requiring a case-by-case approach and examination of each patent application.

Hence, the replication of Section 3(d) as such is not suitable for developing-country settings facing a resource crunch. Further, Section 3(d) provides an element of discretion for the examiners and judges to interpret the term 'efficacy' and it may make these institutions vulnerable to lobbying. The scope of interpretation also may result in the undermining of the policy objective to curb the patenting of known substances by a narrow interpretation by the patent office or the judiciary.

Hence, it is always better for developing countries to provide for an *ex ante* exclusion of patenting of known substances without any substantive examination. Towards this end, what is required is a modified Section 3(d) which does not contain any scope for patenting of known substances in cases of enhancement of known efficacy. ♦

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Pharmaceutical innovation and incremental patenting

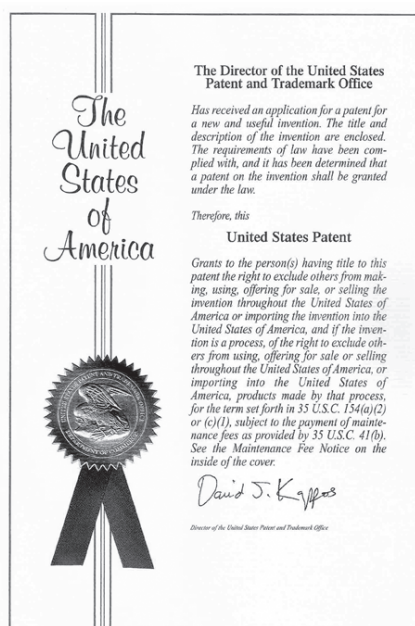
There is now an increasingly widespread view that the role of the patent system in promoting innovation is less substantial than usually claimed. As the pharmaceutical industry today is almost wholly concerned with securing patents by effecting minor improvements on existing patented products, the patent system has moved far away from its objective of stimulating genuine inventions.

Carlos M Correa

THE patent system was devised in order to reward inventiveness, encourage technical progress and foster the dissemination of innovations. The restriction to the free movement of ideas that the granting of a patent entails has been justified under different theories, namely natural rights, moral reward, incentive to invention and encouragement to innovation. The idea that patents are necessary to allow the investor to recoup its investment in research and development (R&D) dominates in current debates and jurisprudence of many countries (Gutterman, 1997).

Although the development and exploitation of numerous contributions to technology have been closely linked to, although not necessarily determined by, the possibility of obtaining exclusive rights to exploit inventions (Archibugi and Malaman, 1991), the patenting system is today far from fulfilling its intended objectives. The expansion of the subject matter of patentability from inanimate to living forms, the admission of broad claims encompassing vast fields of technology, the dilution of the patentability requirements, and shortcomings in the examination process have led to a profound distortion of the system (Jaffe and Lerner, 2004). There is a proliferation of patent applications and grants, in great part motivated by a variety of defensive and offensive patenting strategies (Granstrand, 1999).

One increasingly widespread view is that the role of the patent sys-



A US patent certificate. The large number of patents today is not a reliable indicator of innovation.

tem in promoting innovation is less substantial than usually claimed (Landes and Posner, 2003; Levin et al., 1987). Patents may even stifle the very innovation they are supposed to foster (Jaffe and Lerner, 2004). There is compelling evidence indicating that 'collective invention' based on sharing innovations is more efficient than patenting them (Bessen and Meurer, 2008); some studies suggest that innovation not only thrives in a competitive environment, but that more profit can be generated by inventors in a system based on the broad diffusion and common use and improvement on innovations (Torrance and Tomlinson, 2009).

The large number of patents applied for and granted is not a reliable indicator of innovation. While the

number of patent applications and grants has increased dramatically, notably in the United States but in other countries as well,¹ this growth is not caused mainly by a surge in R&D spending (Bessen and Meurer, 2008, p. 69).

One of the probable causes of such a surge in some jurisdictions is the relaxation of patent requirements by patent offices and courts. The National Academies of the United States, for instance, have taken up the criticism levelled by many academics and sectors of industry and have expressed their concern about the lax application of the patentability standards (National Academies of Science, 2003), especially as regards non-obviousness and usefulness, in the examination and granting of patents. The application of such standards results in many over-broad (Mazzoleni and Nelson, 1998) or 'low quality' patents (FTC, 2003). In the case of the US, it has been found that an inadequate search of previous patents and publications leads patent examiners to overlook novelty and inventive-step problems; in addition, courts have shown a proclivity to weaken the obviousness test (Bessen and Meurer, 2008). Even the users and main beneficiaries of the patent system have become growingly critical about the functioning of the patent system.²

Patents are not granted only when a significant technical development has been achieved. Inventions marked by considerable originality (Merges and Nelson, 1996, p. 128) do not occur frequently, even in highly intensive R&D industries. In fact, the largest part of R&D undertaken (by large

and small firms) is devoted to the improvement and further refinement of existing technologies. Although not all types of incremental innovations may be eligible for patent protection, many actually do. According to a Guide of the Canadian Intellectual Property Office, for instance, 90% of all patented inventions were minor improvements on existing patented devices (Canadian Intellectual Property Office, 1994).

As incremental innovations prevail in most sectors, the patent system has increasingly moved away from its objective of stimulating genuine invention towards a system for the protection of investment in developing incremental innovations, whether truly inventive or not. As a result, for some analysts, 'the time has come not for marginal changes but for wide-open thinking about designing a new system from the ground up' (Thurow, 1997). In fact, an optimal level of patent protection beyond which negative effects would start to dominate positive effects is likely to exist (Guellec, 2007, p. 73). Patents produce a dead-weight burden insofar as the benefits of innovations to society would have been greater in their absence, while they reduce the ability of other firms to exploit innovations on a competitive basis (Maskus, 1997, p. 3). The latter is a critical problem in the case of cumulative systems of technology, where patents may deter rather than promote follow-on innovations.

Pharmaceutical patents

The problems associated with the patenting of minor incremental developments have special implications in the case of pharmaceuticals necessary to protect public health. Patents on pharmaceutical products and processes may be used to block generic competition that lowers prices and enhances access to medicines, particularly by the poor. This may be the case even when the original patent on a medicine has expired and the drug is in the public domain. Patents relating to a known compound (e.g. new formulations, dosages, crystal forms, etc.) are often strategically used to

exclude competitors from the market.³

While the number of newly developed chemical entities has dramatically fallen during the last 15 years (see Figure 1), the number of patents over simple changes in chemistry/formulation of existing pharmaceutical products (e.g. polymorphs, combinations, dosage forms, isomers) has continuously increased. Thousands of patents are granted per year on these incremental innovations, often trivial for a person skilled in pharmaceutical research and production.

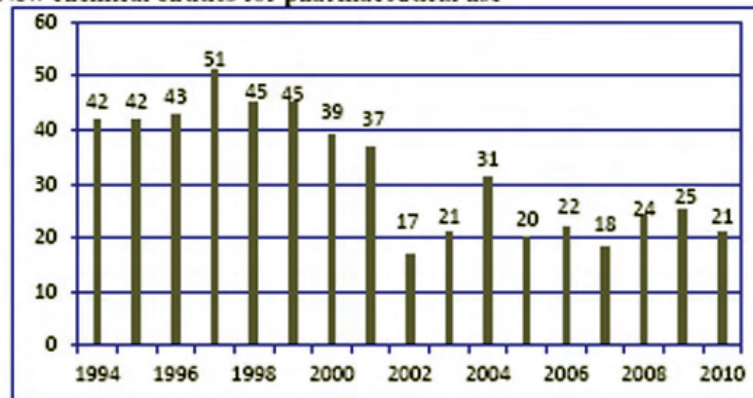
As suggested by Figure 1, the development of new chemical entities for pharmaceutical use presents a worrisome picture. The number of such entities delivered per year has fallen substantially since the 1990s, thereby increasing the average cost of developing new drugs. Furthermore, most new chemical entities do not represent a genuine therapeutic innovation, but present therapeutic effects similar to those of one or more already-marketed drugs (Center for Drug Evaluation and Research, 2005; Spector, 2005).

This decline seems paradoxical for three main reasons. First, since the 1980s and particularly since the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was completed in developed and developing countries,⁴ patent protection has allowed companies to increase income generation worldwide through the ex-

ercise of stronger and, in some cases, longer patent rights⁵ and data exclusivity.⁶ Second, there is a new set of scientific and technological tools – such as genomics, proteomics, combinatorial chemistry – that offer the potential of speeding up drug discovery. Mass screening of potential drug candidates has been substituted by more efficient methods enabling the rational design of drugs. Third, the pharmaceutical industry has been one of the most profitable sectors of the economy, fourth only after mining, crude oil production and commercial banking (Commission on Intellectual Property Rights, Innovation and Public Health, 2006). Moreover, funds allocated to R&D have increased since the last decade.

The fall in innovative productivity may indicate a crisis in the model of drug development carried out by large pharmaceutical companies, as 'the number of new products has not increased whilst the overall level of resources being invested has risen dramatically' (Charles River Associates, 2004). Increasingly, large firms find it more difficult to maintain a continuous pipeline of new and commercially viable products. They heavily depend for new drugs on advances made by small biotechnology companies, while many of the clinical studies are done by specialised contractors and certain segments of biomedical research are undertaken in cooperative ways following an 'open access'

Figure 1
New chemical entities for pharmaceutical use



Source: US FDA.

model, insofar as computational models utilising genetic information become more important as part of the product development process (Maurer, Rai and Sali, 2004).

Patents over minor incremental developments (often termed as ‘evergreening’ patents⁷) may be used to exclude generic competition and thereby block access to affordable drugs. They may constitute an important obstacle to the realisation of the right to health recognised in the International Covenant on Economic, Social and Cultural Rights and, growingly, in the national constitutions of many countries. The reason for this is that patents obtained (including in relation to drugs already in the public domain) are often strategically used to block generic competition, thereby delaying the entry into the market of medicines at a lower cost. This problem affects developed and developing countries alike.

An inquiry by the European Commission, for instance, found that ‘originator companies have designed and implemented strategies (a “tool-box” of instruments) aimed at ensuring continued revenue streams for their medicines. Although there may be other reasons for delays to generic entry, the successful implementation of these strategies may have the effect of delaying or blocking such entry. The strategies observed include filing for up to 1,300 patents EU-wide in relation to a single medicine (so-called “patent clusters”), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, concluding settlement agreements with generic companies which may delay generic entry and intervening in national procedures for the approval of generic medicines. The additional costs caused by delays to generic entry can be very significant for the public health budgets and ultimately the consumer’. The European Commission estimated a loss of around three billion euros due to delays in the entry of generic products caused by misuse of the patent system (European Commission, 2009). The European Commission further found in relation to

219 drugs that:

‘...nearly 40,000 patents had been granted or patent applications (as defined above) were still pending...Of the nearly 40,000 cases, some 87% were classified by the companies as involving secondary patents, giving a primary:secondary ratio of approximately 1:7. Of the applications still pending, 93% were classified as secondary (a primary:secondary ratio of approximately 1:13), whilst 84% of the patents granted were classified as secondary (a primary: secondary ratio of approximately 1:5)’ (European Commission, 2009).⁸

A critical conclusion from this analysis is that current patent strategies in the pharmaceutical industry may have a direct negative impact on access to drugs, as patents on minor variants/improvements of existing products can be used to block legitimate generic competition, which normally lowers prices and makes medicines more affordable. In particular, the grant of such patents may, in some cases, force governments that need to ensure access to medicines for their population to grant compulsory licences, whenever patent owners charge high prices and/or refuse to grant voluntary licenses on reasonable commercial terms.

Although compulsory licences and government use are legitimate under international law, their application has faced considerable resistance from developed countries’ governments and retaliations from the pharmaceutical industry. A basic question that arises out of these cases is whether the grant of the patent was justified in the first place and whether governments can avoid the various costs (including of a political nature) associated with the grant of compulsory licences if they applied more rigorous standards in examining the respective patent applications. ♦

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and Compulsory Licensing (published by the South Centre). The book presents the outcomes of research conducted with the support of the International Development Research Centre (IDRC).

Endnotes

1. China’s State Intellectual Property Office (SIPO) received a record 1.2 million patent applications during calendar year 2010, a 25% jump on the 2009 figure. See ‘Quality is China’s biggest patent challenge’ – available from <http://www.iam-magazine.com/blog/Detail.aspx?g=e81c5421-bccc-4eb5-9895-f347443cf73e>.
2. A survey conducted among large companies (with annual revenues exceeding \$10 billion) by the Intellectual Property Owners Association (IPO) in August 2005 showed that its corporate members perceive the quality of patents granted by the US Patent and Trademark Office to be less than satisfactory. Over half of the respondents, 51.3%, rated the quality of patents issued in the US today as less than satisfactory or poor (47.5% less than satisfactory and 3.8% poor). Those rating the quality as more than satisfactory or outstanding were 8.8% of all respondents (8.8% more than satisfactory and 0% outstanding). The respondents’ prognosis for the future was not encouraging. Over two-thirds of respondents said they would be spending more, not less, on patent litigation over the coming years (PR Newswire, 2005).
3. In Argentina, Uruguay and other countries, for instance, a patent on a process to produce a tri-hydrate form of docetaxel, an anti-cancer drug, was used to exclude off-patent forms of the drug. A patent on a didanosine tablet for slow release of the active ingredient was used in Argentina to block the commercialisation of another, off-patent formulation of the same drug (Levis, 2010).
4. Transitional periods for implementing the TRIPS Agreement were provided for developing countries, economies in transition and least developed countries. Developing countries that previously did not recognise pharmaceutical product patent protection could delay its introduction until 1 January 2005

but only a few countries made full use of this term.

5. The TRIPS Agreement set out a minimum term of 20 years, obliging many countries (including the US and Canada) to change their legislation.
6. In the context of free trade agreements (FTAs), as a result of demands made in the process of accession to the WTO, or by the US government or the European Union, several countries have implemented *sui generis* regimes granting exclusivity over the test data necessary to obtain marketing approval for pharmaceutical products containing new chemical entities. Such exclusivity is not required, however, by the TRIPS Agreement, which only mandates protection of test data under the discipline of unfair competition.
7. 'Evergreening' is generally based on the patenting of minor changes to or derivatives of existing products (e.g. formulations, dosage forms, polymorphs, salts, etc.) in order to indirectly extend the life of the original patent over an active ingredient.
8. Fifty-seven per cent of the 'secondary' patent applications are related to pharmaceutical formulations.

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Deadly rise of ‘superbugs’? It’s business as usual for Big Pharma!

There can be no better illustration of Big Pharma’s obsession with short-term profits than its refusal to invest in the development of new antibiotics to combat diseases caused by the new deadly strains of multi-drug-resistant bacteria. *Shila Kaur* elucidates.

EVEN as the soaring rates of potentially lethal infections threaten to turn into a public health catastrophe, Big Pharma stubbornly refuses to invest in antimicrobial innovation.

The World Health Organisation has warned that without antimicrobial innovation which is needed to combat multi-drug-resistant bacteria that are spreading quickly around the world, there will be a health emergency of global proportions. The recent move by Britain urging the G8 leading industrial countries to take action against antimicrobial resistance through coordinated international action attests to the seriousness of the problem (see ‘UK raises alarm on deadly rise of superbugs’, *The Guardian*, 11 June 2013).

Drug resistance is an inevitable consequence of antibiotics. The drugs wipe out susceptible infections but leave resistant organisms behind. The survivors multiply and, in time, can become immune to even the strongest antibiotics. ‘Superbugs’ and resistant strains in hospitals are currently on the rise.

In efforts to curb the spread of multi-drug-resistant bacteria, healthcare facilities and providers are being told to go back to basics: the focus is on appropriate hand-washing techniques and hand hygiene as well as sanitation as first-line prevention measures. The health community is waking up to the fact that while there is an urgent need for antimicrobial innovation, excellent prevention and control measures must regain the status of standard operating procedure.

According to a status report published in April 2013 by the Infectious Diseases Society of America (IDSA),

only two new antibiotics have been approved in the US since its 2009 pipeline report. Since 1998, only four antibiotics were approved by the US Food and Drug Administration for use by doctors. The last approval came in 2010. Only seven antibiotics are currently in any kind of advanced state of development and are years away from approval and use.

There was a time when 11 Big Pharma companies were involved in antibiotic research and development. Today the figure is down to four: GlaxoSmithKline, Pfizer, AstraZeneca and Merck.

There was a time when 11 Big Pharma companies were involved in antibiotic research and development. Today the figure is down to four.

So what’s keeping Big Pharma away from antimicrobial innovation? According to Helen Boucher, lead author of the 2013 IDSA report, amongst the major encumbrances to antibiotic innovation is the low return on investment. Drug development takes a lot of time and money; drug companies prefer investing in drugs that treat chronic or lifelong diseases which guarantee big returns in terms of profits. Why invest in antibiotics which are typically prescribed for just a few days and are cheap? The returns are comparatively small and

Big Pharma is just not interested.

For example, in Australia, according to the pharmaceutical industry peak body Medicines Australia, it takes about A\$1.4 billion, 10,000 molecules and 12 to 15 years of research and development before a new medicine is approved for use. In 2010 there were more than 2,950 medicines under development, of which more than 800 were cancer drugs, 250 cardiovascular drugs and only 83 were antibiotics.

Big Pharma also complains of another obstacle: the ‘lack of regulatory clarity’ from the US Food and Drug Administration, which has made it increasingly difficult for antibiotic development to surmount all the necessary regulatory hurdles. Critics of this view, however, point out that fast-tracking regulatory approval processes could compromise drug safety. It could of course make antibiotic development more profitable for Big Pharma – at the expense of small pharma which actually focus exclusively on superbugs and other resistant bacteria and are able to reap profits due to smaller overhead costs.

‘There are only a handful of companies like us out there,’ said Steve Gilman, chief scientific officer and executive vice president of Cubist, a bio-pharmaceutical company based in the US. ‘Our guidance for R&D for 2013 is between \$400 and \$420 million, with the bulk of that focused on antibiotics,’ Gilman was quoted as saying in a CNBC.com news report (‘Big Pharma exit: Who’s fighting the superbugs?’, 23 April 2013). ‘Our overhead is much less than a larger firm,’ he added. Cubist reported a net revenue in 2012 of \$926.4 million, up

23% from 2011.

'We've been able to find a steady stream of revenues that keeps growing. We're happy to pursue a \$500 million market, where the bigger firms won't,' he added. 'I don't think the bigger pharmaceutical firms are going to change their mind about getting back into antibiotic research anytime soon. It's up to us [smaller firms] to get involved.'

While antibiotic resistance is threatening public health, for Big Pharma, 'superbugs' requiring treatment are less appealing targets for drug development than chronic conditions such as statin (cholesterol-lowering drugs) and anti-depressants, beta-blockers or anti-rheumatics. Pfizer's cholesterol pill Lipitor remains the best-selling drug worldwide. Its annual sales in 2010 were \$12.9 billion, and its closest competitors were Plavix, a blood thinner from Bristol-Myers Squibb and Sanofi-aventis; Nexium, the heartburn pill from AstraZeneca; and Advair, the asthma inhaler from GlaxoSmithKline.

But not all is doom and gloom. Experts from the medical, veterinary, agriculture, infection control and public health sectors advocate a multi-faceted strategy combining antibiotic stewardship with a comprehensive national resistance monitoring, surveillance and audit system, coordinating education and stewardship programmes and implementing infection prevention and control guidelines.

Peter Taylor, assistant director of Microbiology at the Prince of Wales and St George hospitals and a lecturer in Pathology at the University of New South Wales in Australia, said it well: 'It is important that those with the information use it wisely and do not spread unnecessary fears. The answer lies in excellent diagnosis, excellent care and excellent pharmacy support, as well as continuing education of the medical profession and the community at large.'

The underlying message appears to be: Prevention is still better than cure. ♦

Shila Kaur is a health consultant with the Third World Network.

Unpacking the Issue of Counterfeit Medicines

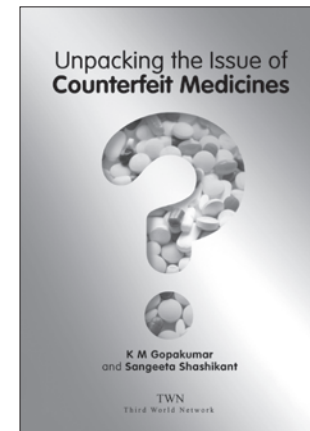
K M Gopakumar & Sangeeta Shashikant

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 pertaining to legitimacy, transparency,



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

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Big Pharma CEOs rake in \$1.57 billion in pay

In the US the big pharmaceutical companies have been raking in huge profits through the price-gouging of government programmes such as Medicare (the scheme which provides healthcare for the old and disabled) and illegal marketing activity. *Ethan Rome* elaborates.

FOR people who were blown away to learn recently that the 11 largest global pharmaceutical companies made an astonishing \$711 billion in profits over the last decade, here's another measure of the industry's greed: the same companies paid their chief executive officers a combined \$1.57 billion in that period. Not bad work if you can get it. They achieved this thanks in part to their systematic exploitation of Medicare and an epidemic of illegal marketing activity.

According to corporate filings analysed by Health Care for America Now (HCAN),¹ in 2012 the drug companies' CEOs drew total compensation of \$199.2 million, two and a half times the total in 2003. In 2006, the first year of the Medicare prescription drug law, the pay of the CEOs jumped by \$58.9 million from the previous year, the largest one-year increase in the decade HCAN reviewed.

Inflated drug prices

These huge spikes in pay coincided with eye-popping profits bolstered by a provision the pharmaceutical lobby inserted into the law to prohibit Medicare from using its unparalleled purchasing power to obtain discounts or negotiate prices with drug companies. By prohibiting Medicare from getting better drug prices, the federal government is effectively subsidising the greed of the drug makers and their CEOs. As a result, Americans pay vastly higher prices than people in other countries for identical drugs. This is ludicrous and wasteful. It hurts the government,



Johnson & Johnson's then CEO William Weldon (pic) took in \$29.8 million in compensation in 2012.

seniors and middle-class families.

It should not be the official policy of the United States to price-gouge our people and government – a practice that's especially offensive at a time when some in Washington are talking about cutting Medicare benefits.

Simply empowering Medicare to buy drugs under the same bulk purchasing discounts used by state Medicaid programmes would save the federal government billions. For example, the Medicare Drug Savings Act, introduced by Senator Jay Rockefeller, would save \$141 billion over the next 10 years without reducing Medicare benefits. Similar measures are in President Obama's budget proposal and the House Democratic budget plan.

Illegal and improper conduct on the rise

The increases in CEO pay and drug-company profits also corresponded with a surge in illegal and improper conduct by the industry. From 2003 to 2012, financial penal-

ties paid by drug manufacturers to settle allegations of illegal marketing, price-gouging of government programmes and other violations rose by more than 500%, according to a report issued by Public Citizen in September 2012.

In 2003, there were only nine settlements with the federal or state governments, amounting to \$967 million in penalties. In 2011, federal and state government agencies reached a record 44 settlement agreements with drug makers. And by July 2012, with the year only half over, drug companies had already agreed to pay nearly \$6.6 billion as part of 19 settlements with the government. Data on the second half of 2012 have not yet been compiled by Public Citizen.

Here's the kicker: The most com-

Total CEO Compensation At Top 11 Global Pharmaceutical Companies, 2003-2012 In USD Millions

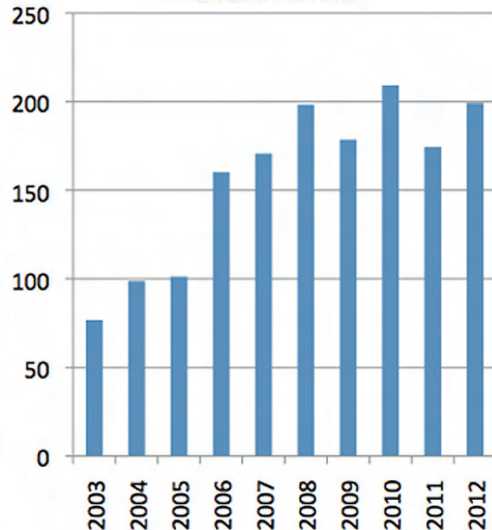
Johnson & Johnson	\$233.4
Abbott Laboratories	\$207.8
Pfizer	\$192.2
Novartis	\$179.1
Eli Lilly	\$160.2
Roche	\$146.7
Merck	\$135.4
Bristol-Myers Squibb	\$130.0
Sanofi	\$70.0
GlaxoSmithKline	\$58.4
AstraZeneca	\$54.5

Total: \$1,568 MILLION
Source: Corporate Filings

mon drug-company violation cited by regulators and law enforcement agencies between 1991 and July 2012 was overcharging government health programmes. Really? How much overcharging do they need?

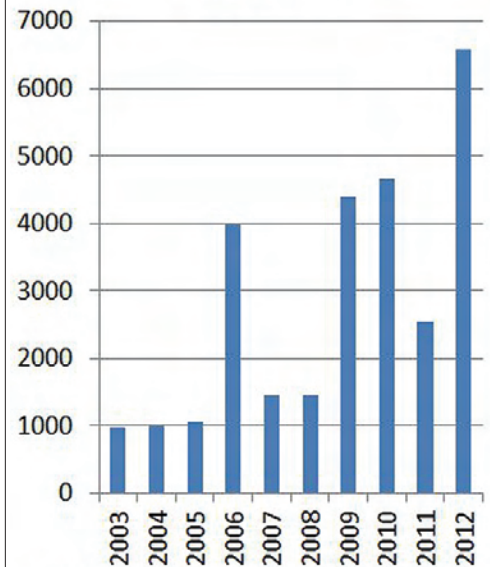
Over the last decade, the drug companies racked up unprecedented penalties for criminal and civil violations. They jacked up prices for seniors and the government. They made excessive profits and gave unconscionable compensation to the CEOs in charge of this all.

CEO Compensation Expenditures, 11 Largest Pharmaceutical Manufacturers
In USD Millions



Source: HCAN Analysis

Pharmaceutical Industry Financial Penalties
in USD Millions



Source: Public Citizen - www.citizen.org/documents/20731.pdf

End corporate tax giveaways

It is obscene that any lawmakers in Washington – even the most extremist Republicans who hate civilisation as we know it – are even talking about cutting benefits for seniors in the midst of what amounts to a drug industry scandal.

We shouldn't be making any benefit cuts to Medicare, Medicaid, the Affordable Care Act or Social Security. Not now, not ever. Instead, we should make the wealthiest Americans pay their fair share in taxes and eliminate indefensible special-interest tax breaks and subsidies for big corporations like the companies that ship jobs

overseas, Big Oil, and a drug industry that has made a science out of ripping off the American people. ♦

Ethan Rome is Executive Director of Health Care for America Now. This article is reproduced from the Huffington Post website (www.huffingtonpost.com).

Endnote

- 1 HCAN's analysis of CEO pay focused on 11 companies: Johnson & Johnson, Abbott Laboratories, Pfizer, Novartis, Eli Lilly, Roche, Merck, Bristol-Myers Squibb, Sanofi, GlaxoSmithKline and AstraZeneca. Over the 10-year period, the \$1.57 billion in total compensation was split among 27 executives. The top earners in 2012 were Johnson & Johnson's William Weldon, who took in \$29.8 million, and Pfizer's Ian Read, who received \$25.6 million. By comparison, the median household income in the US last year was \$50,054, while half of all Medicare beneficiaries had less than \$22,500 in annual income. In April, HCAN compiled data showing that the 11 drug companies reported \$711.4 billion in profits over the same 10-year span.



A nurse attending to an elderly patient in a hospital in the US state of Georgia. The pharmaceutical industry's profits have been bolstered by a provision in US law which prohibits Medicare – the federal healthcare programme for older and disabled Americans – from obtaining discounts or negotiating prices with drug companies.

New study claims over 250,000 died from 2011 Somalia famine, US-Al Shabaab savagery to blame

A new study has revealed that the 2011 Somalia famine was more devastating than previously believed. And while Al Shabaab has rightly been condemned for denying humanitarian aid access to the country's south-central regions it controlled, the fact is that the US, which effectively criminalised humanitarian aid to these regions, was also a silent partner to this crime.

'POWERFUL people have that privilege of denying reality,' the Somali scholar Abdi Samatar stated when explaining the causes of Somalia's 2011 famine as it was laying waste to the population.

The famine was one of history's rare socio-natural calamities in that it was predicted almost a year in advance, providing sufficient time to avert it and at minimal costs for the rich nations. Thus, it will likely go down as one of the most easily preventable calamities in modern history.

It will also go down as one of the most devastating.

According to a mortality study released in May, close to 260,000 people may have died in southern and central Somalia as a result of the 2011 food crisis and famine, 133,000 of whom were children under the age of five.¹ And these were only the 'excess deaths'.

The study claims more than 290,000 deaths 'would have occurred irrespective of the emergency', given the normal state of humanitarian catastrophe in the region, bringing the overall death toll to some 595,000 from October 2010 to April 2012.

For perspective, the 'excess' death toll alone is more than three times higher than the number of deaths from Syria's civil war, according to the figure circulating in the Western press. And it took much less time for the mountain of corpses to pile up in Somalia.

Given the scale of the horror and, more importantly, the cast of culprits,

Stephen Roblin

it was imperative that blame be attributed in a politicised rather than truthful manner.

Silent tragedy

Commenting on the significance of the study, Philippe Lazzarini, the chief UN humanitarian coordinator for Somalia, called the famine a near 'silent drama of tragedy'. His assessment, however, is only partially correct.

Not powerful enough to deny reality to the world, Al Shabaab has been widely condemned in the harshest terms for its barbaric and criminal acts of denying humanitarian access to areas under its control and preventing civilians from migrating to regions where relief could be accessed.

For the other major culprit, it's a different story.

The 'silent' part of the tragedy, at least in the West, has been the United States' responsibility for a famine that resulted in a virtually genocidal outcome.²

Speaking to an Al Jazeera reporter in November 2011, Samatar went on to say how the United States and others 'partner[ed] in a very bizarre way with Shabaab in punishing the local population'.

Echoing Samatar's comments five months later, Ken Menkhaus, a professor of political science at Davidson College and former politi-

cal adviser for the UN in Somalia, explained that the 'suspension of food aid into southern Somalia was the only thing that the US government and Al Shabaab could agree on, to the detriment of [millions] of Somalis'.

Indeed, Washington's partnership with Al Shabaab achieved the near-total dismantling of the humanitarian relief system in south-central Somalia several years before the 2011 famine. And Washington took the lead in this cruel and sordid enterprise.

Before Al Shabaab began expelling Western humanitarian organisations, the Bush administration effectively criminalised humanitarian relief in south-central Somalia by designating Al Shabaab as a foreign terrorist organisation in February 2008. Organisations receiving US funding could then face prosecution if their efforts were deemed as providing 'material support' (a totalitarian legal device that now includes speech) to militants, irrespective of intent.³

Despite US aid restrictions themselves violating international law and the near-famine conditions in Somalia, the Obama administration zealously carried forward its predecessor's effective criminalisation of humanitarian relief after taking office.⁴

In November 2009, the World Food Programme declared, 'The food supply line to Somalia is effectively broken.' This statement came two months *before* Al Shabaab barred the WFP.

The Obama administration broke the food supply line by pulling mil-

lions of dollars of food contributions and funding as a means of coercing humanitarian agencies into agreeing to stifling aid conditions. This resulted in aid agencies drastically scaling back operations and pulling out of the region altogether at a time when Somalia was on the 'brink of famine'.

US cables released by WikiLeaks reveal that the administration knew well in advance that its policies would break programmes directly funded by Washington and 'the broader humanitarian system'.

According to a July 2009 cable from the US embassy in Nairobi, 'The continued delay of humanitarian assistance funds is likely to have a devastating and long-lasting impact on humanitarian operations in Somalia and on the 3.2 million Somalis in need of life-saving assistance.' The cable adds, 'A continued delay in funding would likely result in the rapid scaling down of critical humanitarian activities.'⁵

This is exactly what happened.

From 2008 to 2011, US aid to Somalia plummeted. The combination of the funding decline, US aid restrictions, and Al Shabaab's increasingly hostile stance towards Western aid agencies took the population off life-support.⁶

Somalia went over the brink in the spring of 2011 when the Horn of Africa was hit with its worst drought in 60 years.

It's worth pausing for a moment to note that scientists are linking the drought which sparked the famine to climate change. This should serve as another reminder of the 'cruel irony of the climate crisis', that the 'countries least responsible for producing greenhouse gases... are the countries now at greatest risk of death and human suffering because of climate change', a global threat to which Washington has blocked any meaning international response.⁷

According to the new study, between May and October 2011 there were more than 20,000 famine deaths per month in south-central Somalia. The UN finally declared an official famine in July 2011.

In the midst of the horror, one

sensible idea was put forth from inside Washington. Congressperson Christopher Smith reportedly sent a letter to the Obama administration that called for direct negotiations with Al Shabaab in order to establish a humanitarian corridor.

But rather than rank the plight of starving Somalis over perceived strategic interests, the administration resorted to terror and maintained the obstacles blocking humanitarian relief until it was no longer politically tenable.

Washington reportedly performed drone strikes near the port city of Kismayo on 23 June 2011 and three more strikes on 6 July.⁸ The following day it was reported that Al Shabaab announced it would lift its ban on international aid organisations. Evidently Al Shabaab leaders were divided over the issue. But later that month, the militant group's leadership denied lifting the ban.

One wonders as to the effect of Washington's terror strikes at this critical moment.⁹

Humanitarian gesture?

In the face of international pressure, US officials denied the disastrous impacts of its aid policy. When lying to the world was no longer politically tenable, in August 2011 President Obama gave only a verbal assurance to humanitarian agencies that they would not face prosecution.

The assurance came after some 29,000 were claimed to have died (mainly children), according to the US government's own estimate at the time. *New York Times* editors referred to the US response as 'acting in advance to ameliorate the effects' of the famine, a humanitarian gesture for which the 'Obama administration deserves credit'.

Washington's regional clients also acted in advance to save starving Somalis.

Kenya, Ethiopia and their proxy Somali militias waged a military offensive inside Somalia's southern border during the first half of 2011 – crimes that dramatically worsened the humanitarian crisis in these regions.

As a symbol of Kenya's humanitarian concern, its military shelled a community hospital in a Somali border town, an act Human Rights Watch suspects was deliberate.

Then in October Nairobi outdid itself by launching a full-scale invasion against Al Shabaab. Washington and other Western powers provided swift diplomatic and military support to their ally, while officials from humanitarian relief organisations decried the invasion for preventing humanitarian access to countless starving civilians in the border regions.

Always eager to punish its historical enemy's civilian population, Ethiopia sent its forces in to help 'ameliorate the effects'. For their part, militias affiliated with the Western-backed transitional government, which controlled Mogadishu at the time, committed large-scale theft of food aid.

Denial

US officials are aware of the devastating outcomes of their Somalia policies. Hence, responsibility for the human tragedy cannot be assessed honestly. Political expedience demands that reality be denied.

Menkhaus noted the political imperative of denying reality: 'There are plenty of Western countries, including my own government, who would like to see the conversation stop right there and say it was all Al Shabaab's fault.'

We might add that it's also convenient to ignore how the terrorist group rose to power.

As Jeremy Scahill documents in his new book, *Dirty Wars: The World Is a Battlefield*, Al Shabaab was catapulted to dominance as a result of the US-sponsored Ethiopian invasion and occupation that began in 2006. Prior to this, the CIA triggered a 'full-scale dirty war' on the streets of Mogadishu by hiring Somalia's notorious warlords to carry out assassinations and renditions.

Though these crimes 'may seem [like] unpalatable choices', an embassy cable describes, they were 'the only means . . . available', and there-

fore justified. Much like dismantling the humanitarian relief system can be justified on grounds that it was 'the only means' to avoid paying 'a terrorism tax to al Shabaab'.

And as evidently justified, there's no need for the American public to know when the noble pursuit of 'strategic interests' demands resort to savagery.

While it is true that the powerful often have the privilege of denying reality, it's a privilege we grant when we reduce ourselves to passive recipients of lies. ♦

This article is reproduced from the ZNet website (www.zcommunications.org/znet).

Endnotes

1. The study was commissioned by the Food and Agriculture Organisation of the United Nations (FAO) and the USAID-funded Famine Early Warning Systems Network (FEWS NET). USAID and donors through FAO funded the study.
2. The common figure cited as the death toll in the 1994 Rwandan genocide is 800,000 out of a total population of 7 million at the time, which constituted close to 12% of the population. According to the famine mortality study, an estimated 10.1% of children under 5 years old and 4.6% of the overall population died in central and southern Somalia due to the famine. It should be emphasised that these percentages pertain only to the 'excess deaths' caused by the famine. They are not percentages for the overall death toll (595,000) during the study period (October 2010 to April 2012). Given the massive death toll and the causes of the famine, the use of 'genocidal politics' as a characterisation of the local and geopolitical dynamics responsible for the atrocity is arguably warranted.
3. For analysis of the legal and practical implications of US counter-terrorism legislation on humanitarian agencies, see Sara Pantuliano, Kate Mckintosh and Samir Elhawary with Victoria Metcalfe, 'Counter-terrorism and humanitarian action: Tensions, impact and ways forward', Humanitarian Policy Group, HPG Policy Brief 43, October 2011; Sarah Margon, 'Unintended Roadblocks: How US Terrorism Restrictions Make It Harder to Save Lives', Center for American Progress, November 2011; 'Safeguarding Humanitarianism in Armed Conflict: A Call for Reconciling International Legal Obligations and Counterterrorism Measures in the United States', Charity & Security Network, June 2012; and Kasturi Sen and Tim Morris, 'Civil Society and the War on Terror', International NGO Training and Research Centre, 2008.
4. I say 'effective criminalisation' recognising that US counter-terrorism restrictions themselves contravened international law. Even if aid agencies disregarded US counter-terrorism restrictions, they arguably faced a real threat of US prosecution, despite this threat being based on entirely fraudulent legal grounds.
5. It's worth noting that the cable also predicted that a collapse in US funding would aid in Al Shabaab's recruitment efforts. Discussing the 'real impact of program closure on local staff and immediate family members', the cable warns, 'The resulting unemployment will increase the probability of relapse into harmful activities by youth through recruitment into piracy, Al-Shabaab, and other groups due to lack of meaningful ventures to apply their skills,' adding that 'staff layoffs may cause small household economies that are now sprouting to fall into recession and possibly destitution. In addition, resource-based conflict may increase resulting in further displacement of communities.' The cable also predicted that 'Delayed funding to USAID food aid partners would have a devastating impact on the 2.7 million people currently benefiting from food distributions leaving them susceptible not only to hunger, malnutrition, and further displacement, but also to manipulation and recruitment by extremist groups' (my emphasis).
6. Describing the impact of Washington's humanitarian aid policy towards Somalia at the time of the famine, policy director with Mercy Corps, Jeremy Konyndyk, said, 'While poor access limited the humanitarian community's ability to address needs in the south, the broader collapse in US humanitarian support to the whole of Somalia since 2009 has undermined humanitarian response and preparedness across the entire country.' On 3 August 2011, Konyndyk gave a statement to the US Senate Committee on Foreign Relations Subcommittee on Africa that provides a brief account of the US aid policy in the years leading up to the famine.
7. Graciela Chichilnisky and Kristen A. Sheeran, *Saving Kyoto* (London: New Holland Publishers, 2009), 18.
8. In a moment that elicited absolutely no scandal, on the sidelines of the February 2012 London conference on Somalia, former Secretary of State Hillary Clinton denied the US strikes in Somalia. When asked whether she supported the US conducting airstrikes in Al-Shabaab-controlled areas, she responded by saying, 'We have absolutely no reason to believe anyone – certainly not the United States... is considering that.' It is revealing to compare the non-response to Clinton's fabrication with the scandal sparked by UN ambassador Susan Rice over her alleged lies about the 2012 Benghazi attack that killed US ambassador Christopher Stevens. If instead of Stevens a host of North African civilians were slaughtered, then Rice would probably have been promoted to Secretary of State, not John Kerry. Clinton, on the other hand, is poised for the presidency. The highest office is not threatened by lies that involve dead Somalis.
9. The same month the *Guardian* reported that '[t]he drought and famine have deepened discord among al-Shabaab leaders that has been apparent for some time'. The report goes on to say how some Al Shabaab leaders 'have supported a lifting of the ban on operations of international aid agencies, while others, such as its top commander, Ahmed Cabdi Godane, reportedly opposed the move on the grounds that NGOs might provide intelligence for US drone air strikes'.

The Korean War Gangnam Style

Yves Engler responds to a flippanant comment by a Canadian minister on the Korean War (1950-53) – one of the most brutal and least understood wars of the 20th century.

DO a billion YouTube hits justify a war that left four million dead? A Conservative minister in Canada thinks so.

At a Quebec City celebration of the 70th anniversary of World War II's Battle of the Atlantic in May, Minister of Veterans' Affairs, Steven Blaney, responded to a question about Canadian military sacrifice with the statement: 'There would be no "Gangnam Style" if it had not been for the sacrifice of Canadians, and members of the United Nations who fought off Communism.'

While I enjoy Psy's South Korean hit as much as Minister Blaney, to say it was worth one of the most brutal and least understood wars of the 20th century is a bit of a stretch.

After the Communists took control of China in 1949 the US tried to encircle the country. They supported Chiang Kai-shek in Taiwan, built military bases in Japan and backed a right-wing dictator in Thailand. One of Washington's early objectives in Vietnam was to 'establish a pro-Western state on China's southern periphery'. The success of China's nationalist revolution also spurred the 1950-53 Korean War in which eight Canadian warships and 27,000 Canadian troops participated. The war left as many as four million dead.

At the end of World War II the Soviets occupied the northern part of Korea, which borders Russia. US troops controlled the southern part of the country. A year into the occupation, a cable to Ottawa from Canadian diplomats in Washington, Ralph Collins and Herbert Norman, reported on the private perceptions of US officials: '[There is] no evidence of the three Russian trained Korean divisions which have been reported on



The Korean War left as many as four million dead.

various occasions ... there seems to be a fair amount of popular support for the Russian authorities in northern Korea, and the Russian accusations against the conservative character of the United States occupation in civilian Korea had a certain amount of justification, although the situation was improving somewhat. There had been a fair amount of repression by the Military Government of left-wing groups, and liberal social legislation had been definitely resisted.'

Noam Chomsky provides a more dramatic description of the situation: 'When US forces entered Korea in 1945, they dispersed the local popular government, consisting primarily of antifascists who resisted the Japanese, and inaugurated a brutal repression, using Japanese fascist police and Koreans who had collaborated with them during the Japanese occupation. About 100,000 people were murdered in South Korea prior to what we call the Korean War, including 30-40,000 killed during the suppression of a

peasant revolt in one small region, Cheju Island.'

In sharp contrast to its position on Japan and Germany, Washington wanted the (Western-dominated) United Nations to take responsibility for Korea in 1947. The Soviets objected, claiming the international organisation had no jurisdiction over post-WWII settlement issues (as the US had argued for Germany and Japan). Instead, Moscow proposed that all foreign forces withdraw from Korea by January 1948. Washington demurred, convincing member states to create the United Nations Temporary Commission on Korea (UNTCOK) to organise elections in the part of Korea occupied by the US. For its part, the

Soviet bloc boycotted UNTCOK. Canada joined UNTCOK even though Prime Minister Mackenzie King noted privately 'the [US] State Department was simply using the United Nations as an arm of that office to further its own policies.'

The UN-sponsored election in South Korea led to the long-term division of that country and Canada's involvement in a conflict that would cause untold suffering. On 10 May 1948 the southern part of Korea held UNTCOK-sponsored elections. In the lead-up to the election left-wing parties were harassed in a campaign to 'remove Communism' from the south. As a result left-wing parties refused to participate in elections 'wrought with problems' that 'provoked an uprising on the island of Cheju, off Korea's southern coast, which was brutally repressed'.

After the poll Canada was among the first countries to recognise the Republic of Korea in the south, effectively legitimising the division of

the country. External Affairs Minister Lester Pearson sent Syngman Rhee, who became president, a note declaring 'full recognition by the Government of Canada of the Republic of Korea as an independent sovereign State with jurisdiction over that part of the Korean peninsula in which free elections were held on May 10 1948, under the observation of the United Nations Temporary Commission'. Conversely, Ottawa refused to recognise the North, which held elections after the South, and opposed its participation in UNTCOK reports. For Pearson the South held 'free elections' while those in the North 'had not been held in a democratic manner' since the Soviets did not allow UNTCOK to supervise them. After leaving office Pearson contradicted this position, admitting, 'Rhee's government was just as dictatorial as the one in the North, just as totalitarian. Indeed, it was more so in some ways.'

The official story is that the Korean War began when the Soviet-backed North invaded the South on 25 June 1950. The US then came to the South's aid. As is the case with most official US history, the story is incomplete, if not downright false. Martin Hart-Landsberg notes in his book *Korea: Division, Reunification, and US Foreign Policy*: 'The best explanation of what happened on 25 June is that Syngman Rhee deliberately initiated the fighting and then successfully blamed the North. The North, eagerly waiting for provocation, took advantage of the southern attack and, without incitement by the Soviet Union, launched its own strike with the objective of capturing Seoul. Then a massive US intervention followed.'

Korea was Canada's first foray into UN peacekeeping/peacemaking and it was done at Washington's behest. US troops intervened in Korea and then Washington moved to have the UN support their action, not the other way around.

The UN resolution in support of military action in Korea referred to 'a unified command under the United States'. Incredibly, United Nations forces were under US General Doug-

las MacArthur's control yet he was not subject to the UN. Canadian Defence Minister Brooke Claxton later admitted, 'The American command sometimes found it difficult to consider the Commonwealth division and other units coming from other nations as other than American forces.'

After US forces invaded, Ottawa immediately sent three gunboats. Once it became clear US forces would not be immediately victorious, Canada sent thousands of ground troops into an extremely violent conflict.

Two million North Korean civilians, 500,000 North Korean soldiers, one million Chinese soldiers, one million South Korean civilians, 10,000 South Korean soldiers and 95,000 UN soldiers (516 Canadians) died in the war. The fighting on the ground was ferocious, as was the UN air campaign. US General MacArthur instructed his bombers 'to destroy every means of communication and every installation, factory, city and village' in North Korea except for hydroelectric plants and the city of Rashin, which bordered China and the Soviet Union, respectively.

A *New York Times* reporter, George Barrett, described the scene in a North Korean village after it was captured by UN forces in February 1951: 'A napalm raid hit the village three or four days ago when the Chinese were holding up the advance, and nowhere in the village have they buried the dead because there is nobody left to do so. This correspondent came across one old woman, the only one who seemed to be left alive, dazedly hanging up some clothes in a blackened courtyard filled with the bodies of four members of her family. The inhabitants throughout the village and in the fields were caught and killed and kept the exact postures they had held when the napalm struck – a man about to get on his bicycle, 50 boys and girls playing in an orphanage, a housewife strangely unmarked, holding in her hand a page torn from a Sears Roebuck catalogue crayoned at Mail Order No. 3,811,294 for a \$2.98 "bewitching bed jacket – coral". There must be almost two hundred dead in

the tiny hamlet.'

Canadian troops denigrated the 'yellow horde' of North Korean and Chinese 'chinks' they fought. One Canadian colonel wrote about the importance of defensive positions to 'kill at will the hordes that rush the positions'. A pro-military book notes dryly that 'some [soldiers] allowed their Western prejudices to develop into open contempt for the Korean people.'

'Korea was a man-made hell with a place among the most violent excesses of the 20th century.'

Cold War Canada summarises the incredible violence unleashed by UN forces in Korea: 'The monstrous effects on Korean civilians of the methods of warfare adopted by the United Nations – the blanket fire bombing of North Korean cities, the destruction of dams and the resulting devastation of the food supply and an unremitting aerial bombardment more intensive than anything experienced during the Second World War. At one point the Americans gave up bombing targets in the North when their intelligence reported that there were no more buildings over one story high left standing in the entire country ... the overall death toll was staggering: possibly as many as four million people. About three million were civilians (one out of every 10 Koreans). Even to a world that had just begun to recover from the vast devastation of the Second World War, Korea was a man-made hell with a place among the most violent excesses of the 20th century.'

But, it was all worth it, according to the current Conservative government in Canada. After all South Korea has given us 'Gangnam Style'. ♦

Yves Engler is a Canadian activist and author. His latest book is The Ugly Canadian: Stephen Harper's Foreign Policy. The above article is reproduced from his website YvesEngler.com.

Where land is power

The landless peasant farmers occupying large landholdings in Pará, the Brazilian state where the land conflict is most violent, face threats ranging from intimidation by armed private guards to the spraying of toxic agrochemicals over their homes and crops.

Fabiola Ortiz

TOILING beneath a blazing sun in the humid heat of the Amazon, Waldemar dos Santos, 60, tends the community garden he shares with other landless peasant farmers in the Brazilian state of Pará, as they wait for agrarian reform to provide them with the opportunity for a better life.

‘My dream is a small plot of land. Our goal is to bring an end to hunger in this country, which is falling off the precipice of need,’ he told *Tierramérica**. As a child, dos Santos fled the drought-stricken northeast Brazilian state of Bahia and migrated to the northern state of Pará, in Brazil’s Amazon region.

His family is one of the 280 families living in the Frei Henri des Roziers Camp, established by the Landless Rural Workers’ Movement (MST) on 8 August 2010. The camp is named after a Dominican friar and lawyer from the Catholic Pastoral Land Commission who continues to fight in defence of human rights in the region at the age of 82.

The landless peasants are occupying a 400-hectare estate known as Fazendinha, located off federal highway BR-155 roughly 100 kilometres from the city of Marabá. They say that the purported owners of the estate, formerly a cattle ranch, created it by invading and illegally deforesting public land, and that at the time of the occupation, it had been left idle and unproductive.

This is the justification for almost all of the land occupations by social movements demanding agrarian reform in Brazil.

In the southeast of Pará, where the struggle over land is most violent,



Children at the Frei Henri des Roziers Camp established by the Landless Rural Workers’ Movement (MST).

over 500 settlements of small farmers have been legalised by the National Institute for Colonisation and Agrarian Reform (INCRA). But there are still more than 100 camps of families living in tents and straw huts waiting for the federal government to grant them legal ownership of the land.

It takes an average of five years to get the government to confiscate a property and allocate the land to agrarian reform.

Bitter conflict

To reach the Frei Henri camp, you need to drive along a long stretch of the dusty BR-155, full of potholes and trucks loaded with minerals that block the road day and night.

The region was once rich in cashew trees, which were razed to make way for cattle pastures. Right

in the heart of the Amazon, the towering green canopies and exuberant vegetation of the rainforest were replaced with the flat monotony of grassland years ago.

The occupation of Fazendinha has led to bitter conflicts with local ranch owners, who have joined forces and hired private armed guards to intimidate the landless farmers and destroy their crops.

‘We plant crops to grow healthy food. The ranch owners don’t produce anything and claim that their lands are productive. We face constant threats. Justice in Pará is very slow. We wait and despair,’ said dos Santos.

‘Here, land is power,’ declared Maria Raimunda César, 39, a member of the MST coordinating committee in Pará. ‘The conflict is never-ending. In Pará, people are gunned down like animals. A side of beef for export is worth more than a human life.

Fabiola Ortiz/IPS

There is tremendous injustice, and growing oppression and violence.'

According to César, agrarian reform is ignored in national policies. Both the current government of Dilma Rousseff and that of her predecessor Luiz Inácio Lula da Silva (2003-11) 'removed the issue from the agenda'.

Changes in land use tend to follow a similar perverse pattern, said César. First the rainforest is opened up to make way for mining and logging for charcoal production. This is followed by the invasion of public lands by private landholders, who destroy the forest and plant grasses for cattle grazing.

On average, there is one head of cattle per hectare, she noted.

Airborne threat

Also along highway BR-155, but close to Marabá, there is another camp of landless peasant farmers, the Helenira Resende Camp, which was set up on 1 March 2010 and is now home to 150 families. In addition to intimidation by armed men, these farmers also face airborne threats: toxic agricultural products sprayed over their homes and fields.

Raúl Montenegro, an Argentine activist who participated in an international mission in solidarity with the landless peasants of Pará, told Tierramérica that 'the combined use of bullets and poisons is tantamount to chemical warfare against these communities.'

'The large landholders claim that they are spraying these chemicals on their own lands, but this is a way of evading responsibility,' said Montenegro, the president of the Foundation for the Defence of the Environment, based in Córdoba, Argentina, and a recipient in 2004 of the Right Livelihood Award, known as the 'Alternative Nobel Prize'.

'We were not only able to confirm that groups of armed men laid siege to an entire community and subjected them to a nightly hail of gunfire and loud bombs at the Frei Henri des Roziers Camp. We also witnessed how companies like Santa Barbara conduct aerial spraying of pesticides,'



A gathering of the MST which is demanding agrarian reform in Brazil.



The government of President Dilma Rousseff (pic) has 'removed the issue [of agrarian reform] from the agenda', according to a landless workers' activist.

he denounced.

'This poison reaches children, adolescents and adults, with total impunity, with no government control, and no epidemiological or environmental testing,' he added.

'Our motto is to occupy and resist, but they are an extremely powerful group. The men at the ranch are heavily armed and they shoot,' said Aldemir Monteiro de Souza, 28, a resident of the Helenira Resende Camp, which occupies 50 hectares within the Cedro ranch, an estate covering a total area of almost 15,000

hectares.

The 'powerful group' he is referring to are the owners of the cattle company Agropecuária Santa Barbara. One of the company's biggest shareholders is banker Daniel Dantas, who was arrested in 2008 for financial crimes and money laundering.

According to the MST and the Pastoral Land Commission, in the last 10 years alone, the Santa Barbara Group has bought up 800,000 hectares of land in six municipalities in Pará.

'The group appropriates public lands, uses slave labour, and commits environmental crimes,' said Charles Trocate, an MST coordinator in Pará.

The landless peasants are waiting for INCRA technicians to inspect the Cedro ranch to determine if it is productive and legal. If irregularities are detected, the process for its expropriation will begin, and the land will subsequently be allocated in parcels to the farmers.

A hearing with the INCRA agrarian oversight committee has been scheduled for 22 May at the Justice Forum in Marabá. This will be the first step, after years of occupation and the establishment of the landless farmers' camp. — IPS

* This story was originally published by Latin American newspapers that are part of the Tierramérica network.

Activists call for review of Myanmar's citizenship law

Myanmar's citizenship law has left some 1.2 million people stateless and without rights. The worst victims of this injustice have been the 800,000 Rohingya, who have become one of the most persecuted people in recent times. It is time to enfranchise the disenfranchised, say human rights activists.



Myanmar's citizenship law has left more than 1.2 million people, including the Rohingya (pic), stateless nationwide.

HUMAN rights groups are calling for a review of Myanmar's citizenship law, which has left more than 1.2 million people stateless nationwide, according to the UN Refugee Agency (UNHCR).

'The 1982 citizenship law should be amended to reflect basic principles of human rights, including equality and non-discrimination,' Debbie Stothard, the coordinator for Altsean Burma, a Bangkok-based advocacy organisation for minority rights in Myanmar, told IRIN news service.

There are no reliable data on the number of stateless people in Myanmar; the last population census was conducted more than three decades ago, according to the UN Population Fund. But rights groups believe that in addition to some 800,000 stateless Rohingya in Myanmar's western

Rakhine State, ethnic groups originating from China and India are also disenfranchised by the law, facing persecution without legal redress.

'The law creates a permanent underclass that is exploited with impunity, creating significant resentments [liable to] explode when security forces take advantage of the legal vulnerability of stateless persons through abuse,' said Phil Robertson, the deputy director of Human Rights Watch's (HRW) Asia division.

While all persons born on Burmese soil were considered citizens under the country's earlier 1948 citizenship law, provided one parent was Burmese, General Ne Win's seizure of power in 1962 led to policies that further excluded communities whose ancestors entered the country after 1823.

The constitution established by Ne Win in 1974 listed 135 'national races' – including the Karen, Shan and Kachin – while excluding all 'non-indigenous' minorities.

Eight years later, the citizenship law, which recognises only the children of national races as full citizens, was established, leading to limited rights for non-recognised groups such as the Rohingya.

Parliament blocks amendments

Despite repeated calls for change, including a recent attempt to amend the law on 6 November 2012 by Member of Parliament (MP) Tin Mya from the Union Solidarity and Development Party, objections from other parliamentarians caused proposals for amendments to be shelved, according to Altsean.

'While the international community has [also] spoken up to the need to amend the law, there has yet to be a coordinated and concerted effort to ensure this actually happens,' said Stothard.

The discriminatory law may have helped fuel the sectarian violence that broke out between the Muslim Rohingya and the Buddhist population in Rakhine State in June and October 2012 and in the town of Meiktila in March 2013, said Chris Lewa, the director of the Arakan Project, a Rohingya advocacy group.

'The Rohingya have been constant victims of arbitrary arrests, extortion, harassment and fines due to their precarious legal status and laws prohibiting basic rights such as freedom of movement,' she said.

Children ‘blacklisted’

Since 2005, Rohingyas in Rakhine State – who must obtain permission to marry or travel outside of their villages – have been limited to having two children per couple.

But with access to birth control limited around the country, Burmese couples have an average of 4.7 children per marriage. The majority of Rohingya families continue to have more than two children, but are unable to register those over the limit or fear being penalised, says Lewa.

‘These children are blacklisted and without any rights at all,’ she explained. ‘They cannot even apply for permission for marriage, to go to school or to move outside of their village with their parents because, according to the authorities, they do not exist,’ she added.

In November 2012, immigration police and the national army in the Rakhine townships of Pauktaw, Maungdaw and Sittwe attempted to register Rohingya families, issuing them temporary national residency cards (NRCs). But these efforts were met with opposition because the registration forms used the term ‘Bengali’ to describe the Rohingyas – a label referring to their South Asian heritage, used to emphasise their perceived foreignness.

‘It is very controversial as they deserve full citizenship, not just temporary residence, which gives them no other rights, and they are afraid that if they sign the documents then it will be proof that they are non-citizens,’ said Lewa.

Additionally, to receive the NRC, families must prove they have lived in Myanmar for three generations, but many Rohingyas lost evidence of this in the recent sectarian violence, which destroyed up to 4,800 buildings, according to HRW, and forced over 125,000 to flee their homes.

Missed opportunity

Myanmar has undergone significant reforms since March 2011 – including the easing of media censor-



Sectarian violence broke out between the Muslim Rohingya and the Buddhist population in Rakhine State in June and October 2012. Picture shows the debris of houses that were burned down during the conflict.

ship, the release of hundreds of political prisoners and the reshuffling of the country’s cabinet. The European Union subsequently lifted sanctions on Myanmar on 22 April 2013.

But rights groups fear international pressure to create an inclusive and fair citizenship law will cease to be effective.

‘We are worried that the rights of Rohingya and other stateless people will continue to be set aside in the international euphoria over Burma’s reforms,’ said Altsean’s Stothard.

In the week of 29 April, the Inquiry Commission on the Sectarian Violence in Rakhine State, a govern-

ment commission set up to investigate the 2012 violence in Rakhine, failed to recommend any revisions to the citizenship law. Rather, it called for a process to examine the citizenship status of the people in Rakhine, in order to implement the provisions of the current law.

‘The commission missed a critical point when it failed to include reform of the 1982 Citizenship Act to strip out discriminatory provisions and ensure that the law complies with international human rights standards,’ said HRW’s Robertson on 29 April. – *IRIN humanitarian news and analysis service* ♦



Children at a camp for displaced Rohingyas in Sittwe, Rakhine State. Since 2005, Rohingyas in Rakhine have been limited to having two children per couple.

Female garment workers bear brunt of tragedy

It is women, who make up 80% of the workforce in Bangladesh's booming garments industry, who have borne the brunt of the unending cycle of industrial accidents in this sector. The latest, one of the worst industrial accidents in history, was no exception.

Suvendrini Kakuchi

EARLIER this year, 18-year-old Shapla was just another one of thousands of garment workers employed in a factory in Savar, a suburb of Bangladesh's capital Dhaka.

Today she is a handicapped survivor of one of the worst industrial accidents in history: the collapse on 24 April of the massive Rana Plaza, a building housing five factories, that buried scores of workers under a wave of cement and glass, killing over 1,100 people.

'I am desperate about the future,' Shapla said, echoing the sentiments of hundreds of female apparel workers like her who lost their limbs on that fateful day.

The young mother is now recovering in a hospital in Dhaka after her hand was amputated. Having survived the collapse, Shapla is considered one of 'the lucky ones', but she is loath to see the bright side, as her handicap will almost certainly prevent her from finding work.

Experts say that women, who make up 80% of the workforce in this country's booming garments industry, have borne the brunt of this tragedy. According to initial reports, over 80% of those who lost lives and sustained injuries in the collapse were women.

'They are now socially and economically heavily disadvantaged,' said Mashud Khatun Shefali, founder and head of Nari Uddung Kendra (the Centre for Women's Initiatives).

A leading advocate for female garment workers' rights, Shefali says her organisation, which has lobbied for better conditions such as safe housing for workers, is now focusing



Eighteen-year-old Shapla, a garment worker who survived the Rana Plaza collapse, lies on a hospital bed in Dhaka.

on helping female survivors overcome the trauma of the accident.

Some of the workers are 'so badly affected that they say they never want to work in factories again', Shefali told Inter Press Service (IPS). 'They need long-term physical and mental rehabilitation...and they need to be accepted as disabled persons by their families and society.'

A woman named Nazma Begum, whose legs have been amputated as a result of her injuries, told a local television station that she 'worried incessantly' about how she would handle her disability, until her husband assured her of his continued support and love.

The dark side of manufacturing

Over the last decade, Bangladesh – a country of 150 million of which 49% live below the poverty line – has become a crucial player in the international apparel trade by providing a vast supply of cheap labour.

Bangladesh's garment industry is

now the third largest in the world after China and Vietnam, bringing in \$20 billion or roughly 80% of the country's annual foreign exchange.

Major apparel companies based in the West and wealthy Asian countries like Japan and South Korea began shifting their production centres to Bangladesh when old manufacturing hubs like Thailand began to raise wages.

Mass-produced and bargain clothes that include such labels as Gap, Primark, H&M, Walmart, Sears and American Apparel are all manufactured here and then sold in the importing countries.

More than 5,000 factories employing over 3.5 million workers are packed into high-rise buildings in Dhaka and outlying districts, operating round the clock.

The biggest to the smallest of these factories are staffed by mostly young women hailing from rural areas, who come to the cities in the hopes of acquiring skills they have no access to in Bangladesh's agricultural regions.

When they arrive in the city, they often live together in close quarters, sharing bathrooms and food.

Uneducated and illiterate, these women have few means by which to earn a steady income; their vulnerability makes them easy prey for manufacturers who claim that, in order to remain 'competitive' on the world market, they must hire the cheapest possible workforce.

According to Shefali, young women often start off as interns, meaning they do not receive a wage but instead labour for a stipend that can be as low as \$1 per month.

Within a year, they move on to operating more sophisticated machinery and drawing a regular salary, she added.

Most women sew, wash and pack garments for roughly \$30 to \$40 a month, working a daily average of 10 hours, seven days a week. In contrast, men tend to be hired for high-level positions, such as quality control and management.

Hazardous

The garment sector has been hailed as one of the country's biggest employers, bringing a steady wage to thousands of women. But a string of tragedies has recently highlighted the hazardous nature of this work.

Last November, over 100 garment workers perished in a fire in the Tazreen Fashion Factory on the outskirts of Dhaka. Survivors of that trag-

Cutting corners to compete

BUSINESSMEN like Zahangir Kabir, owner of the Dhaka-based Rahman Apparels, agree that garment workers are forced to labour in tough conditions, but claim that employers, too, are 'under heavy pressure'.

He told IPS smaller garment companies like his are expected to meet high trading standards or else accept huge losses.

Kabir owns two factories – one for sewing and the other for denim washing – on the crowded outskirts of Dhaka. His 500 employees, the majority of them women, produce clothing such as jeans and denim jackets for European and US markets.

But the strict quality standards

and deadlines imposed by parent companies in the West often cannot be met in Bangladesh.

'Unexpected political upheavals and regular power outages mean we cannot deliver goods cheaply or meet deadlines. Even a slight default allows the buyer to reject our products,' he explained.

While Bangladeshi suppliers work for the promise of tidy profits, they also face massive risks in the 'cut-throat capitalist market'.

'This is the key reason businesses are reluctant to support higher labour standards, including higher wages, for the workers,' he said, adding that he welcomes stricter monitoring of the industry.

edy claim they tried to escape, but were locked in by the factory managers.

Similarly, on 24 April, employees were threatened with dismissal if they failed to come to work, despite warnings that the eight-storey building, which only had a permit to house five floors, was unsafe. A week before the incident large cracks had begun to appear on the ceilings, prompting engineers to issue warnings that a collapse might be inevitable.

Negligence of workplace safety is just one of many labour violations women workers face. Sometimes they are forced to work 14-hour shifts in order to turn around a quick profit for

the factory owners.

Still, activists point out that in a Muslim country with high poverty rates, the garment industry provided a rare opportunity for women to leave their homes and raise their status from housewives to breadwinners.

This increased economic independence enabled them to exercise more autonomy in their own lives, to choose their own husbands and enter into marriages on more equal terms.

But the Savar tragedy has dealt a hefty blow to this hard-earned status.

Sharmin Huq, a retired professor at Dhaka University who specialises on the handicapped sector, fears that social discrimination will make life harder for the women than ever before.

Those who survived the tragedy will likely lose their jobs, as their injuries will prevent them from performing at the level demanded by factory owners.

Huq told IPS that generous donations pouring in from countries like the United States and Germany to help the survivors must be channelled directly towards 'the large number of [affected] female workers, to help them re-start their lives'.

This includes support for everything from acquiring artificial limbs to accessing regular counselling to deal with the trauma of the tragedy. – IPS



The collapse of Rana Plaza, a building housing five factories, was one of the worst industrial accidents in history.

Thatcher: A requiem

For former British premier Margaret Thatcher (October 1925 - April 2013), the freedom of the markets was the highest liberty and she chained the people indissolubly to them, says *Jeremy Seabrook*.

IN one of her last public appearances, Margaret Thatcher is seen coming out of 10 Downing Street after a visit to David Cameron. She is wearing a pale blue suit, her hair is in its characteristic frozen spun-sugar halo. She has to reach for the railings to steady herself. Who, seeing a figure so reduced and enfeebled, could fail to be moved to compassion?

It is a quality for which she herself had small regard, especially towards those communities whose historic purpose was wiped out during her premiership from 1979 to 1990. Revenues from North Sea oil at the time maintained the high value of the currency and made imports so cheap they obliterated much of Britain's industrial base, especially coal, steel and manufacturing. This created a bitterness which, 25 years later, had not abated: in some pit-villages there were spontaneous celebrations over her death; a potent contrast with what the *Daily Mail* said was a Britain bidding 'an affectionate farewell to Baroness Thatcher'.

Transformational

Thatcher was 'transformational'. She possessed the charisma of the obsessive, the individual in the grip of a single idea. And indeed, her intensity made of her an incarnation, a physical symbol of a process that would erase 200 years of industrialism from Britain. She drew upon herself both unstinting adoration and deep loathing; and the woman herself served as a useful lightning-conductor for the epochal shift occurring in British society and economy, as well as in the wider world. Her admirers saw her as Britannia, and without irony, although she presided over the eclipse of much that had been characteristically British, and heralded the coming of transnational culture – the



Margaret Thatcher possessed the charisma of the obsessive, the individual in the grip of a single idea.

worship of wealth, celebrity and glamour, which obliterated all that was homely, distinctive, and especially working-class, in British life. It is said that, in her memory, a museum and library are to be set up in order to 'keep her ideas alive'. This should not be difficult: the proposed library would be an exiguous collection indeed, for what would it contain beyond the collected works of Milton Friedman – Thatcher's 'intellectual freedom fighter' as opposed to Nelson Mandela's 'terrorist' – and Hayek's *The Road to Serfdom*?

When she died, the air was filled with ideological lamentations; but as soon as she was despatched to the crematorium in Mortlake, and her ashes joined those of her husband at the Royal Chelsea Hospital, the media, almost gratefully, it seemed, consigned her, the monotheist of Political Economy and assassin of socialism, to oblivion.

The funeral itself was a macabre festival of snobbery and pomp, displaying imperial archaisms of precedence (not quite a state funeral, but

a ceremonial send-off with military honours, tribute to her imperial fantasy that shed real blood in the Malvinas); a sanctimonious establishment elevated her to premature sainthood, and the government invoked her to lend an aura of sanctity to its own continuity with her malign project.

Repudiation

Her trajectory from provincial grocer's daughter, a frugal, thrifty life over the shop in a small town, in which her father, Alderman Roberts, was a significant political figure, is generally interpreted as having formed her worldview. If he did, her subsequent political career was a repudiation of all he stood for. The values of localism and frugality she is supposed to have learned at her father's knee were jettisoned; she wrecked local government, and abolished the Greater London Council, and also took Britain into the great global debauch of money that came with the City Big Bang in 1986, the deregulation and exaltation of finance. This is the very reverse of all that she is believed to have assimilated in the way of prudence and caution from the lower-middle-class respectability of Grantham and her Methodist heritage. Perhaps the only memorable act which may be attributed to her small-town upbringing was her introduction of Section 28, which banned anything that could be interpreted as the 'promotion of homosexuality'; a miserably prejudiced measure, against the repeal of which in 2003 an enfeebled Thatcher was ushered into the House of Lords to vote.

She was no conservative. In fact, she wanted to conserve nothing, not even wealth where it was already concentrated, because under her, the making of money became the supreme

good, and indeed brought to prominence many people, some of modest talent but large ambition, in the fields of entertainment, business, public relations and finance. Of course, making money was scarcely new, but she presided over a free market which invaded spaces from which it had been formerly excluded; and having trodden down the barriers, it set up its own temples in monoliths of steel and glass, shrines at which Thatcher's long pilgrimage may be said to have ended. It is, perhaps, fitting that she died in the Ritz – a sojourn subsidised by its owners, the Barclay brothers, also proprietors of the *Daily Telegraph*, ardent admirers of Thatcher. Not for her the pinched existence of the infirm elderly in care homes; unable to manage the stairs in her London home in Belgravia, she retreated to that fabulously expensive almshouse to end her days. 'Let them die in the Ritz' might be carved on her tombstone.

For Thatcher the freedom of markets was the highest liberty, and she chained the people indissolubly to them. Single-minded and relentless, she dismantled state involvement in the economy. To her heirs and assigns she bequeathed the task of deconstructing the welfare state, the next logical step in the epic project of this bogus conservative enterprise.

Cameron called her a great Briton, a patriot, and spoke – in one of those historic echoes Britain does so well – of her lion-hearted love of country. This is also mummery. Her commitment was not at all to the pious parochialism of the corner shop, small businesses, much less to the workers; her passion was for the supranational realm of wealth, which acknowledges no homeland but nestles in tax havens, remote imperial islands, or floats above the earth in private jets, settling only on citadels well guarded against the invader. This is not love of country, for if this had animated her, she would have been moved by the plight of ruined communities and wrecked livelihoods, the result of the transformation of the material and moral landscapes of Britain.



Thatcher drew upon herself both unstinting adoration and deep loathing.

Something she did bring to politics from her early years was played out within the Conservative Party. Was her distaste for the 'wets', the last vestiges in the Tory party of *noblesse oblige*, the one-nation tradition, a remnant of the humiliations she – and her father – had perhaps suffered, when the family were still purveyors of groceries to patricians in fine houses who rarely paid their bills and treated tradespeople with condescension and scorn? When she came to power, were the 'wets', as she called the old grandees, perceived as remnants of provincial gentry who resisted the disposal of public goods in her orgy of privatisation, and her vision of a country, which, she warned in an early speech, was to become 'a less cosy, more abrasive place'? Perhaps, too, her branding of the African National Congress as a 'terrorist organisation' owed something to the monochrome xenophobia of her pinched upbringing, as did her notorious remark about people 'swamped' by immigrants.

The legend runs – and she is already mythologised as the warrior queen, a late Boudicca, an embodiment of Britannia – that the country in which she came to power was in ruins. It was just after the 'winter of discontent', when public service workers had been on strike, the dead were unburied, garbage strewn the streets and union pickets stood in angry knots around braziers compelling those who wanted to work to turn back. According to David Cameron,

she saved the country. What he didn't say was that she saved it from the Labour Party, but the subtext is there, as is his own desire to repeat this political rescue-mission. Tory mythology runs that she lifted Britain from its knees and enabled us to walk tall in the world once more. Deeply unpopular in the initial stages of her premiership – as unemployment rose, there were riots in Liverpool and Brixton – she was saved by the Malvinas conflict, which allowed her to replay in miniature a ruling of the waves. The theatre of nostalgia continues to have potent electoral appeal in Britain.

Agent and emblem

Actually, the exhaustion of Communism and of its weakly offspring, social democracy, was already clear when she came to power. The world was ripe for the second coming of political economy, deregulation, liberalisation, and the 'integration' of Britain into a world economy, no matter what forms of social disintegration occurred in the process. She was agent and emblem, but no initiator of this process. She may have supplied Ronald Reagan with the ideological rhetoric, but this only rationalised changes that had been under way for many years. Even the de-industrialisation of Britain was well advanced before she came to power, since the national division of labour was already giving way to its global



A mass picket by coal miners in Yorkshire in the UK in 1984. The miners were one of the communities whose historic purpose was wiped out in the period of Thatcher's premiership.

successor.

Thatcher's defeat of the unions was accomplished by the erasure of the industries which had made them necessary in the first place. Coal-mining had for two centuries been the bedrock of the country's industrial wealth; pit-villages across Britain were laid waste, their people left to the consolations of drugs, drink and unemployment. Thatcher exemplified the joke of Brecht: if the government didn't like the people, it should change them. The people were indeed changed, and even the memory of industrialism was obliterated; a sad forgetfulness, made more poignant by her own affliction in the last years of her life, as she became more disoriented and detached from the reality she had helped bring about.

Ideological bequest

For Thatcher, actions spoke louder than words; and true to this axiom, she said barely one memorable thing, and proffered no piece of wisdom, for all her 11 years in power. She was illuminated solely by the in-

ner grace of which, in the puritanical nonconformist tradition, wealth was the outer sign.

Yet her inheritance is inescapable. She terrified the Labour Party into acquiescence in her money-drenched view of the world. This produced Tony Blair, an interregnum before her true ideological heirs would come into their own, Cameron, Osborne and Clegg, who carry forward her 'revolution' by tearing down, discreetly but unmistakably, the last vestiges of the welfare state, and privatising the health service. This will ensure that each individual will be forced to make her or his private accommodation with the vast impersonal forces of capital, or perish.

The banking crisis, widening inequality, the indifference of free markets to mere people, the raising of business into a force of redemption, and the making of profit into the true calling of humanity – this is her bequest. The most fateful of all her utterances was actually not hers at all; it originated with her guru, Sir Keith Joseph: 'There Is No Alternative,' she declared. This apparent absurdity was

derided at the time; but as the years have passed, it has become part of the common wisdom, and its significance is only now being registered. For if all other ways of ordering human affairs have indeed been cancelled, and capitalism is uncontested (for that is what she meant), these words, far from representing the triumph of freedom, are its death-knell. If it is true, the liberties fought for and re-asserted by this benign providential figure are negated. An absence of alternatives locks us permanently into the compulsions of a single system; and Thatcher, doughty warrior of the free world, set it on the way to a deepening captivity.

In that shop on a Grantham street corner in the early 1930s, was it the exotic whiff of tea, coffee and cocoa, the smell of cloves, pepper and fragrant rice which filled the nostrils of Margaret with the heady scent of a globalisation to come, the rationalisation of production in a world governed by the deepest unreason? ♦

Jeremy Seabrook is a freelance journalist based in the UK.

Considered as one of the leading modern poets of Latin America, the Ecuadorian poet *Jorge Carrera Andrade* (1902-1978) was also a historian, author and diplomat. The poem below is emblematic of his deep love of both nature and his native Quito.

Biography for the Use of the Birds

Jorge Carrera Andrade

I was born in the century of the death of the rose
when the motor had already driven out the
angels.

Quito watched the last stagecoach roll,
and at its passing the trees ran by in good order,
and the hedges and houses of the new parishes,
on the threshold of the country
where slow cows were ruminating the silence
and the wind spurred its swift horses.

My mother, clothed in the setting sun,
put away her youth in a deep guitar,
and only on certain evenings would she show it
to her children,
sheathed in music, light, and words.
I loved the water-writing of the rain,
the yellow gnats from the apple tree,
and the toads that would sound from time to time
their bulging wooden bells.

The great sail of the air manoeuvred endlessly.
The mountain range was a shoreline of the sky.
The storm would come, and at the roll of its
drum
its drenched regiments would charge;
but then the sun with its golden patrols
would bring back translucent peace to the fields.

I would watch men clasp the barley,
horsemen sink into the sky,
and the wagons filled with lowing oxen
go down to the coast fragrant with mangoes.

The valley was there with its farms
where dawn touched off its trickle of roosters,
and westward was the land where the sugarcane
rippled its peaceful banner, and the cacao
held close in a coffer its secret fortune,
and the pineapple girded on its fragrant cuirasse,
the naked banana its tunic of silk.

All has gone now, in sequent waves,
like the futile cyphers of the foam.
The years go leisurely entangling their lichens,
and memory is scarcely a water-lily
showing on the surface timidly
its drowned face.

The guitar is only a coffin for songs,
and the head-wounded cock laments.
All the angels of the earth have emigrated,
even the dark angel of the cacao tree.

Translated by Donald Devenish Walsh