

ST 8TH DAY MAY25 2008

Cover Story: TAKING ON GOLIATH

WHAT brings together Archbishop Desmond Tutu; US Congressman Henry Waxman; European parliamentarians; Global Fund director Michael Kazatchkine; Ruth Dreifuss, former Swiss President and chair of the Who Commission on Intellectual Property Innovation and Public Health; Stephen Lewis, Former UN special envoy on Aids in Africa; author John le Carré; German development minister Heidemarie Wiecek-Zeul; Norwegian minister for international development Erik Solheim; and a host of Indian and international NGOs?

They have all expressed support for the “Drop the Case” campaign against Swiss pharmaceutical giant Novartis, manufacturers of the cancer drug Glivec/Glivec, in what could be a landmark case for the drug industry and consumers — both Indian and global. In fact, the unfolding Novartis drama is being keenly watched as not only will the outcome impact both manufacturers and consumers economically and health wise, it but will also set a precedent that will rearrange drug patenting and pricing policies globally, apart from affecting the philanthropic work of a host of NGOs. In India, there needs to be that much more interest since every individual will be directly affected by the turn of events.

The “Drop the Case” campaign was launched against Novartis by Médecins Sans Frontières or “Doctors Without Borders” — an international humanitarian aid organisation that provides emergency medical assistance in more than 70 countries and is the winner of the 1999 Nobel Prize for best medical relief.

In India, “Boycott Novartis” is a campaign launched by the Drug Action Forum – Karnataka, along with a few other NGOs. They are urging consumers and particularly the medical fraternity to boycott all Novartis products. The reason why doctors have been addressed is because they hold the key to a patient’s choice of medicines. A patient will only buy what the doctor prescribes, even if cheaper alternatives are available.

To understand the campaigns, it is necessary to get an insight into the patent scene and the Novartis litigation. People’s participation will go a long way in creating a healthy drug policy. As of now, it is almost nobody’s baby — the petroleum and chemicals ministry lays down policy and the commerce ministry decides pricing. Hence it is easy for large multinationals to confuse the government with technical jargon and misleading data into toeing their line.

The most striking global success of the Indian pharmaceutical industry has been its ability to provide drugs, particularly for treating HIV/Aids, at an affordable price. Until 2000, anti-retroviral (ARV) drugs were not affordable to the vast majority the world over. Multinational drug companies priced ARV drugs between \$12,000-13,000 annually per person. But since 2000, prices began falling after Indian manufacturers introduced less expensive generic versions – currently for as low as \$140 annually per person, thanks to the absence of a product patent regime in India. At present, India supplies generic drugs

to more than 210 developed and developing countries.

India amended its Patents Act in 2005 and introduced product patent to comply with the Trade Related Aspects of Intellectual Property Rights (Trips) agreement. This agreement, while providing a 10-year transition period (1995-2005) to developing countries to introduce a product patent regime, made it obligatory for them to provide five years' Exclusive Marketing Rights until the patent is granted or rejected. In India, EMR is allowed only on satisfaction of two prerequisites, namely: product patent and marketing approval in a foreign country; and marketing approval and product patent application in India.

The introduction of a product patent in 2005 has been seen as a threat to the generic drugs industry. Section 3 (d) of the Indian Patents Act was an attempt to safeguard the operating space for the generic industry through limiting the scope of patentability. Hence, the challenge to Section 3 (d) is being viewed as an attempt to undermine India's sovereign right to frame its laws as well as its right as an international player to use flexibilities available within the Trips pact.

Among the range of flexibilities incorporated in the Patents Act, the following are relevant in the current context: Section 3 (d) that limits the scope of patents; and pre-grant opposition which permits the opposition of patents by any person/organisation prior to the grant of the patent.

In 1993, Novartis filed patent applications for the cancer drug imatinib in most countries. At that time India did not grant product patents. In 1998, Novartis applied for a patent on imatinib mesylate — the beta-crystalline polymorph of the mesylate salt of imatinib — in India. It is sold under the brand name Glivec in Europe/Australia and Gleevec in the USA, and is used to treat Chronic Myeloid Leukaemia, a variant of blood cancer. In future, the compound could be used to treat other types of cancers like glioblastoma multiform, pulmonary fibroids, solid tumours, etc. In November 2003, Novartis obtained an EMR for Glivec under the then existing provisions of the IPA. Natco, the sole generic manufacturer of Glivec, challenged the decision of the Patents Office ruling on EMR in Delhi High Court. In 2004, the Cancer Patients Aid Association went to the Supreme Court challenging the EMR pending decision on its patent application. The CPAA argued that the EMR prevented Indian drug companies from manufacturing and marketing the drug and would make the treatment unaffordable to thousands of patients in India. In 2005, India opened a patent mailbox (where all patent applications were kept in the interim period). In January 2006, the patent on imatinib mesylate was rejected in India on the grounds that it only represented a new form of a known substance.

Hence it was not an innovation and could not be patented under Indian law. In May 2006, the company filed two writ petitions in Madras High Court: first to appeal against the patent rejection; and then to challenge the constitutional validity of Section 3(d) of the IPA, saying it contradicted Article 27 of the Trips agreement, under which World Trade Organisation-member states must provide patent protection in all fields of technology, without exception.

On 6 August 2007, Madras High Court rejected Novartis' challenge of Section 3 (d) of the IPA as it had no jurisdiction over intellectual property rules of the WTO — only governments, not companies, could approach the WTO for redressal — even rejecting the appeal that Section 3(d) violated Article 14 pertaining to the right to equality. On 7 August 2007, the Swiss government refused to take it up with the WTO through a letter

by the Federal Councillor, Department of Economic Affairs for the Swiss Confederation, which stated that “we must have a reliable Trips system and the one in India is good enough. The Swiss government never gets involved in any judicial pronouncements of other countries”. The judgment was welcomed globally by healthcare activists and public interest groups. The high court transferred the first petition to the Intellectual Property Appellate Board. Novartis then went to the high court asking for the exclusion of Ipab technical member S Chandrasekaran, from hearing its appeal. It argued that he was biased because, as a government official during the patent hearings, he had filed an affidavit against the company. The appeal proceedings were stayed pending hearing. On 8 October 2007, the Centre informed the court that the patent cell of Ipab could exclude Chandrasekaran, former Controller General of the Indian Patent Office, and the cell comprising the chairman and vice-chairman could go ahead with the hearing. On 12 November 2007, Novartis told Madras High Court that it agreed to the Union government’s proposal of excluding a technical member from the Ipab patent cell to hear its appeal. The next day, the court ruled that a two-member bench comprising the Ipab chairman and vice-chairman (Justice MHS Ansari and ZS Negi, respectively) could look into the rejection of the Novartis patent application on its cancer drug Glivec. Section 3 (d) the IPA, 2005, states that “(d) 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 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.

“Explanation: For the purposes of this clause, salts, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”

Section 3 (d) aims to prevent the successive patenting of mildly variant forms or derivatives of known substances after expiry of the monopoly period — a practice popularly called “evergreening” of patents, followed by many pharmaceutical companies to extend patent monopoly after the expiry of the original patent. This is seen as part of a strategy multinational pharmaceuticals adopt to prevent WTO-member countries from invoking the flexibilities available within the Trips agreement. In the past, pharmaceutical giants resorted to litigation to block measures that would enable broad access to medicines. In 2000, for instance, 37 drug companies, including Novartis, challenged the South African patent statutes that empower the health minister to issue a compulsory licence and import generic versions of patented medicines if needed to safeguard public health. A powerful international campaign forced this global group to drop the case.

In the current Novartis case, despite national and international campaigns to drop it, the pharmaceutical multinational has refused to give up litigation in India. The health ministers of India and Germany, members of the European parliament, the Norwegian international development minister and even US Congressmen are among those who have demanded the case be withdrawn. The Swiss government, too, does not back the Novartis case.

The campaign is important because:

n If product patent is granted to Novartis for imatinib mesylate, Indian generic versions

will be forced to go out of the market and the treatment of CML, restricted to Glivec, would cost Rs 1.2 lakh per six-week cycle — well beyond the reach of 99 per cent of the patients needing Glivec. The difference in prices of generic versions of drugs and the original product is huge and this alone is indicative of increased prices in the new product patent regime;

n Patents confer complete manufacturing monopoly and pricing freedom for as long as 20 years. The prices of drugs may go up by five to 10 times as is evident from the difference in the prices of drugs in India (generic versions) and the prices of drugs in other countries where product patents have been in force, such as Pakistan. To give just one example, according to a CUTS International comparison, the drug Aciclover costs Rs 33.75 in India while it sells at Rs 363 in Pakistan. While these prices may have changed since the study was made, the ratio of difference is likely to remain nearly the same. That there will be a steep rise in prices once a drug is patented is almost a foregone conclusion;

n If Novartis wins this case, other MNCs will seek patents for similar, already well-known medicines, maybe with insignificant variations, thus putting a whole range of medicines beyond the reach of most Indians. India, now known as the “Pharmacy Of The Third World” is the largest supplier of drugs, particularly generic formulations, to several developing and under-developed countries at affordable prices;

n Eighty-five per cent of HIV patients being treated by Doctors Without Borders depend on Indian generic ARV medicines, as do 50 per cent of People Living With AIDs in the Third World;

n Sixty-seven per cent of medicines exported from India go to developing countries; Indian companies provide approximately 50 per cent of the essential medicines Unicef distributes in developing countries;

n Seventy-five to 80 per cent of all medicines distributed by the International Dispensary Association are made in India; in Zimbabwe, 75 per cent of medicines for all public sector health facilities are sourced from India; and

n Hundreds of patent applications on drugs pending with the Indian patent office could be challenged under Section 3 (d).

On its website, Novartis denies it has any intention of blocking generics, yet it has filed cases against all existing and potential manufacturers of the generic form of Glivec.

When its plea was rejected by Madras High Court, Novartis went “forum hunting” to strengthen its “cause” by filing cases from Bombay and Delhi High Courts as well, since the ruling of the high court of one state is not binding on that of another.

Novartis denies that patents and EMRs will lead to a price rise. However, it is significant that immediately after grant of the EMR, Novartis increased the price of Glivec from \$90 to \$2,610. Natco, a generic company, launched the generic version of Glivec in January 2003, at one-tenth the Novartis price. Novartis also denies that granting the patent will affect the flow of inexpensive drugs to other countries. It must be recalled that in 2000, Novartis was among the 37 pharmaceutical companies that nearly stifled South Africa’s access to affordable drugs through the campaign against the country’s patent laws.

Novartis admits that the price of Glivec is way beyond the reach of most Indians, but says it has a programme to address this. Accused of pricing Glivec beyond reach, it points out that 99 per cent of patients in India who consume Glivec receive it free from Novartis under the Glivec International Patient Assistance Programme. That is, 5,151 people in India till March 2006. In India, every year approximately 25,000 new cases of CML are

reported and nearly 18,000 people die. Thus, Glivec offers a lifesaving solution to thousands. Yet the vast majority of people cannot access the drug due to its high price. It is the generic alternatives that meet this need.

However, groups like the CPAA point out that the preconditions attached to the Gipap make it an impossible option; for instance, to qualify, patients must not have any insurance coverage. It was widely believed that the Gipap was being used to promote the market for Glivec — a case reportedly filed by a Chennai doctor claimed Novartis was conducting clinical trials under the guise of Gipap. It was also discovered that a key component of Gipap, known as “Max Patient Advocacy Work”, had been carried out with the ultimate aim of getting Novartis reimbursed for the “free” medicines it was distributing through Gipap. Soon after these controversial issues were raised, Novartis suspended its free distribution programme in India.

Which suggests that if cheaper generic versions are not available, people would continue to be crushed under treatments that could cost, annually, at least five times their annual income! Yet, there is no justification for such exorbitant pricing.

To explain, Glivec is listed as an “orphan drug” (a product that treats a rare disease affecting fewer than 200,000 Americans) under the Orphan Drug Act. This brings down the research and development cost by almost 50 per cent. Normally, clinical drug trials need to be carried out on more than 5,000 people, but as an “orphan drug”, Glivec carried out studies on only 1,027 people. The ODA provides tax sops as well as speeds up approvals for marketing — three years versus the eight-year wait for normal drugs. Thus, orphan drugs begin to recover costs and even earn profits much earlier.

Moreover, multinationals’ claim that R&D costs are responsible for the high prices does not hold water. And dangling the research carrot is no temptation for India. Today 90 per cent of the world’s diseases receive only 10 per cent of R&D money. Between 1975 and 1997, multinational drug companies brought 1,233 new medications into the market and only one per cent (13 medications) were specifically designed to treat major tropical diseases haunting the Third World.

Healthcare activists and public interest groups have welcomed the campaigns and the judgment nationally and globally. But after judgment was pronounced, Novartis expressed concern that the ruling would discourage multinationals from investing in drug innovation and research in India. This essentially means that it and other big drug manufacturers will not introduce new medicines in the Indian market nor would they make any R&D investments in India and patients, therefore, would not be able to access new drugs.

This perhaps was meant to scare the Indian consumer and the government into letting Novartis have its way. However, ground realities show that there is no cause for concern. It must be remembered that Novartis, or any other multinational, invests for profit. So all investments in India are made not out of concern for the poor ailing Indian who cannot afford expensive drugs, but because the skill/labour/infrastructure costs afford huge profitability. And as long as that remains available, they will continue to invest — patent or no patent laws.

Facts, however, have revealed that the contribution of MNCs to R&D in India is not only negligible but also showed a decline during 1999-2004 when Intellectual Property protection was strengthened.

With a strong consumer-friendly law already in place, it is important that drug

prescribers, and, more importantly, drug users understand the need to protect their interests. The Novartis case will set a precedent for others and, therefore, decide our ease of access to and choice of lifesaving drugs.

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TAKING ON GOLIATH



RESULT OF INDIAN PATENT ACT 1970

The effects of generic competition June 2000-June 2006



12000 US\$
10000 US\$

Lowest originator \$10439

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