NOVARTIS INDIA LIMITED

annual report 2006-2007

NOVARTIS

caring and curing

CONTENTS

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R. Shahani	Vice-Chairman & Managing Director
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Dr J. Acebillo	
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Members are requested to bring their copy of the Annual Report to the meeting. Members are also requested to direct all correspondence relating to shares to the Company's Registrar and Transfer Agents, Sharepro Services, at the address above.

Annual General Meeting

11:00 am 20th July 2007

Y.B. Chavan Auditorium
Yashwantrao Chavan Pratishthan
Gen. Jagannath Bhosale Marg
Next to Sachivalaya Gymkhana
Mumbai 400 021

Innovation is the central issue in economic prosperity

– Michael Porter

Dear Shareholder

Today we are witnessing astounding medical progress. Many infectious diseases can be prevented or effectively treated thanks to new medicines and vaccines. Survival rates for children suffering from cancer have doubled in the last 25 years, while the incidence of strokes and heart attacks have significantly reduced. Medical progress has positively changed the lives of millions of patients around the world and ...

...Innovation is the key to this remarkable progress.

Yet, millions more are *still* being left behind with diseases that are curable with modern medicines – destroying lives. There is no quick and easy solution – fighting disease is costly and complex, especially against the backdrop of poverty.

It is with this background that I take this opportunity to sensitize you to a pivotal issue facing the pharmaceutical industry in India specifically to innovation and more broadly, the Indian economy as well.

Even as this year's annual report goes to print, the Madras High Court is deliberating on a petition filed by Novartis appealing against the Indian Patent Office's rejection of a patent for its ground-breaking cancer drug Glivec and challenging a provision in the Indian Patents Act 2005.

The opposition to the Glivec patent is based on widely held misconceptions. This is the belief that patents result in restricting patient access to medicines and that generics is the only answer to the problem. The reality is that access to medicines is a function of the state of a country's healthcare infrastructure and its accessibility, availability of trained staff and delivery systems. Good governance in these areas has to be tackled at national levels by governments. Diluting intellectual property protection and giving copycat manufacturers licence to produce does not result in reaching medicines to the poor.

Another misconception is that if innovation is incremental it does not deserve protection from a nation's patent laws. This shows a lack of understanding of how science works. Incremental innovation is the way in which the vast majority of advances in medical science have occurred and in fact, is the major means by which the health of patients worldwide has been and can continue to significantly improve. It is also an area of research activity in which India has very well developed skills.

However, the Novartis case raises much broader issues which go far beyond whether it gets a patent for Glivec or not. These range from access to innovative medicines by patients in India, to the future direction of pharmaceutical research and ultimately to India's ability to attract investment from research-based industries.

The link between protection of intellectual property and economic prosperity is well documented. This is apparent in the significant mismatch between the Foreign Direct Investments (FDI) flowing into India – despite having the world's second largest pool of scientific manpower – and countries like China or even Singapore.

If India has to close this gap, attract FDI and further accelerate its economic growth, a free and fair regime of intellectual property protection is essential. Promotion of this intangible infrastructure will benefit both Transnational companies and Indian companies. Indian companies will be able to unleash their creative potential and be globally competitive. This will also help ensure that millions have access to medicines, that their lives are transformed and that they reap the benefits of economic growth.

Many thanks to you, our shareholders for the trust you continue to place in Novartis.

Ranjit Shahani

Listen to the Exhortation of the Dawn!
Look to this Day!
For it is Life, the very Life of Life.
In its brief course lie all the
Verities and Realities of your Existence.
The Bliss of Growth,
The Glory of Action,
The Splendor of Beauty;
For Yesterday is but a Dream,
And Tomorrow is Only a Vision;
But Today Well Lived Makes
Every Yesterday a Dream of Happiness,
And every Tomorrow a Vision of Hope.

– Kalidasa

Kerul Patel's tryst with Chronic Myeloid Leukemia (CML) began when he was admitted to a hospital in 2003 for dengue and his blood tests showed that his White Blood Corpuscle (WBC) count was much too high. For this 36-year-old construction professional and father of a year-old son, the news was shattering and life-altering.

A fighter to the core, besides being a fitness freak, Kerul soon took control of his life. Four years later, not only is he back to sprinting four kilometers every day but has even helped raise funds for cancer research by participating in the Terry Fox run earlier this year. The biggest ordeal for him today, he jokes, is getting admission for his son in a school of their choice. It was as if one moment he had death staring him in the face and the next Glivec® held out to him the promise of living a quality life.

Pramod John George, 36, also discovered his CML when he took a routine blood test during a dengue prevention camp organized in his housing complex. This media industry veteran and occasional Sunday School teacher decided to fight it. Three years later he continues to lead a normal life, commuting one-and-half-hours to work, pursuing his hobbies and holidaying with his family.

A beauty consultant, 47-year-old Veronica Noronha discovered she had CML after bouts of giddiness and losing weight at an alarming rate. She quit her job in Qatar and returned to India, hoping to fight the disease with the help of her family. Three years on, she runs a beauty salon from home, and has little time for rest as she prepares for her daughter's wedding, planned for this December.

Sriram Ranganathan, 28, discovered he had CML during the course of a routine blood test prior to taking up a software assignment in the US in 2001 when he was just 22. With help from family, friends and his employer, he battled on. He got married about a year and a half ago and today leads a happy, normal life.

A year into his marriage, Bangalore-based Dr Shital Kiran was diagnosed with CML in 2004. To him, it seemed the world had come to an end. Three years later, he is successfully combating the disease and is a proud father of twins.

These are just five out of over 7,200 stories of heartbreak, pain, despair, heroism and hope of CML and gastro intestinal stromal tumour (GIST) patients from India. Novartis is proud that it has played a pivotal role in empowering these remarkably courageous individuals to fight their ailment by developing a little orange pill, Glivec, the world's first drug specifically designed to fight cancer-causing molecules; and by initiating the Glivec International Patient Assistance Program (GIPAP™). Each of these over 7,200 patients is treated with Glivec and all of them are getting the drug, costing around Rs 101,000 a month, absolutely free.

Novartis is doing this because it is committed to serving patients worldwide by providing innovative, superior medications, which are effective against diseases that could not previously be treated adequately or at all. The company's main purpose is to discover, develop and successfully market innovative products to cure diseases, to ease suffering and to enhance the quality of life.

Glivec is the first drug designed to target only the molecules causing CML

Currently 7200 CML patients receive Glivec totally free through GIPAP

It is to fulfill this commitment that Novartis is fighting a legal battle in the Madras High Court. The company has challenged a denial of patent for Glivec by the Indian Patent Office under Section 3(d) of the Indian Patents Act 2005. It has also asked the High Court to declare Section 3(d) unconstitutional and in breach of India's obligation under the Agreement on Trade-Related Intellectual Property Rights (TRIPS).

The petition goes to the root of the debate about intellectual property rights, patents, innovation and patient access to medicine. The decision of the Madras High Court will decide the future of innovative medicines in India. It is, therefore, necessary for you as Novartis India shareholders to understand the background to the case and fundamental issues at stake.

BACKGROUND

Glivec is the first drug that was specifically designed to target molecules causing CML,

leaving healthy cells intact, opening up new avenues for treatment of cancers. Such has been its efficacy in treating two rare forms of cancer – CML and GIST – that doctors the world over have hailed it as a magic bullet.

The base compound of Glivec, *imatinib mesylate*, was patented worldwide in 1993. No patent was filed in India that time since Indian laws did not allow pharmaceutical product patents.

India joined the World Trade Organisation (WTO) in 1995, beginning a 10-year transition to bring its patent laws in alignment with TRIPS, a multilateral agreement setting out the minimum standards of protection provided to WTO member countries on intellectual property. Novartis applied for a patent for the base material of Glivec, *imatinib mesylate* in crystalline form. It was granted marketing approval for Glivec in December 2001. The drug was launched in India in April 2002.

A few months later, Novartis launched GIPAP in India. One of the most far-reaching patient assistance programs in the world, GIPAP provides Glivec free of cost to eligible patients who cannot afford to pay for it and do not have insurance or other forms of reimbursement. Patients who are on GIPAP receive Glivec as long as they need it. Today more than 99% of patients who are on Glivec in India receive it free of charge from Novartis. The program covers over 7,200 patients in India and under the program, Novartis has so far distributed Glivec globally valued at over $450 million.

In November 2003, Novartis was granted Exclusive Marketing Rights (EMR) for Glivec via an interim provision for providing intellectual property protection until the Indian patent law took effect in 2005. It was the first pharmaceutical company to be granted such rights for a product. The EMR protected the drug for five years, or until review of the patent mailbox application.

In April 2005, to fulfill its obligation to WTO/TRIPS, India enacted the Indian Patents Amendment Act introducing product patents for pharmaceutical products. The Indian law provides for additional criteria for patentability with Section 3(d). In January 2006, citing Section 3(d) of the new law, the patent application for Glivec was rejected. The Indian Patent Office held that the beta crystalline form of *imatinib mesylate* did not satisfy requirements of novelty and inventiveness. The rejection of the patent terminated the EMR.

GIPAP was launched in India in 2002

In August 2006, Novartis filed a petition in the Madras High Court challenging the rejection of the patent as well as asking the court to declare Section 3(d) unconstitutional and not in compliance with India's treaty obligations under TRIPS.

CURRENT STATUS

The legal proceedings have been split into two parts. As we go to print, the newly appointed Intellectual Property Appellate Board, formed under the aegis of the Indian Patents Act 2005, will hear the appeal against the rejection of the patent for Glivec.

In August 2006, Novartis filed a petition in the Madras High Court challenging the rejection of the Glivec patent

The Madras High Court is hearing the challenge to the constitutionality and non-TRIPS compliance of Section 3(d) of the Indian Patents Act. Through the petition, Novartis is seeking clarity on how India values and protects intellectual property. Arguments in the case have been completed and the matter is now under deliberation of the Court.

INTERNATIONAL PRESSURE

Ever since Novartis filed the petition, some international aid agencies and other local Non-Governmental Organisations (NGOs) have launched a campaign trying to get Novartis to withdraw the petition and accept status quo.

Broadly the campaign raises three critical issues and misconceptions. These are:

- The beta crystalline form of *imatinib mesylate* that Novartis seeks to patent is a trivial compound and the move to patent it is an attempt at "evergreening".

- If Novartis wins its legal challenge to Section 3(d) of the Indian Patents Act 2005, it would

adversely impact global supply of life-saving medicines from India, especially those related to the treatment of HIV/AIDS.

● If Novartis wins the case, it will deny access to cheap generic medicines to poor patients.

These misconceptions are based on a lack of comprehension of the basic issues. The reality is different.

Evergreening: The term refers to the practice in which the patent holder seeks to patent trivial or useless modifications of an already existing molecule to extend its monopoly beyond the 20-year period granted by the original patent.

Novartis, which has always adhered to the highest ethical standards, frowns at such practices. But more importantly, calling the move to patent the beta crystalline form of *imatinib mesylate* as an attempt at evergreening exhibits a complete lack of understanding of the issue.

The beta crystalline form of *imatinib mesylate* is an innovation worthy of a patent. The beta crystalline form of *imatinib mesylate* is not some minor modification nor is Glivec a newer form of an older compound. It is Glivec, the breakthrough life-saving medicine that has transformed the treatment of leukemia and other rare cancers, giving new life to patients.

Glivec has been universally hailed as one of the medical breakthroughs of the 20th century. It is the first drug to specifically target cancer causing molecules while leaving other cells intact, thereby ushering in a whole new paradigm in the treatment of cancer.

The 1993 patent was for synthesizing the molecule of *imatinib*; this molecule, however, did not result in a drug that could be used to treat patients and represented only the first step in the process to develop Glivec.

Novartis developed the mesylate salt of *imatinib* and then the beta crystal form of *imatinib mesylate* to make it suitable for patients to take in pill form. Glivec was launched globally in 2001, and this is the only form of Glivec that Novartis has marketed. It has been patented in over 40 countries, including nations like China, which became members of the WTO much later than India.

Novartis case and impact on supply of HIV/AIDS medicines: The Novartis case is about denial of patent to a specific drug and a provision in the Indian Patents Act 2005, which denies incremental innovation. It is unrelated to HIV/AIDS.

A grandfather clause in the Indian Patents Act in any case protects all the currently available generic versions of patented drugs including HIV/AIDS medicines or indeed Glivec, which were launched before 2005. These will continue to be available for the domestic market and for export.

Further, while all pharmaceutical products, including HIV/AIDS medications, have been patentable in India since 2005, many second-line HIV/AIDS treatments are new chemical entities (NCEs) and therefore patentable under the existing Indian patent law regardless of the outcome of this case.

The access to medicines by poor patients is about making medicines available and not patents

Novartis fully supports flexibilities in the TRIPS agreement that allow governments to make exceptions to patent rights and import pharmaceuticals produced under compulsory license in case of a national emergency or a lack of supply from the patent-holder. The Novartis case does not challenge any of these provisions.

Novartis has always actively supported and continues to support other ways to increase access, such as public-private partnerships and shared contribution models in addition to donation programs.

Novartis believes that by denying patents and thereby stifling innovation, Section 3(d) of the Indian Patents Act 2005 actually harms the interests of patients and future generations as it makes access to life-saving medicines like Glivec difficult. It effectively denies the crucial role that incremental innovation plays in research and development of new medicines.

Glivec has been patented in 40 countries, including China

Access to medicines by poor patients: Access to medicines by poor patients is not about patents, it is about making medicines available. Despite over 95% of the medicines classified by the World Health Organisation (WHO) as essential being off-patent, over a third of the world's population has no access to them. In sub-Saharan Africa this figure is as high as 50 per cent.

Barriers to access to medicines are more fundamental – political, financial and even logistical. Improved access to healthcare is as much about existence of trained healthcare staff and infrastructure, accessibility of healthcare facilities and quality of care as affordability. Unless these issues related to lack of diagnosis, infrastructure and distribution are solved, poor people in developing countries will continue to suffer, irrespective of the availability of generics.

That patient access to medicine is not solely dependent upon generics is amply illustrated by India's own example. Indian generic companies are said to be major suppliers to the developing world for HIV/AIDS medicines, yet only 7% of the HIV/AIDS patient population in India – the highest prevalence in the world – who need antiretroviral therapy receive it.

In percentage or value terms, Indian generic companies export much more to developed countries where they can get a better price than they do to the developing world or even in the domestic market.

Generic versions cost ~ 4.5 times the average annual income in India

Even in the case of CML and GIST, generic versions of Glivec are presently available in India. But these generic knockdown versions cost about $2,100 or about 4.5 times the average annual income in India, making them unaffordable to most patients.

Clearly, generics are not the only solution. What is needed is for governments, NGOs and companies to work together to find innovative solutions to these issues. For example, India, along with Africa, has the highest incidence of diseases like malaria, leprosy and tuberculosis that the presence of a large and thriving generic pharmaceutical industry has done little to reduce. The only way to combat these diseases is by innovative medicines. Novartis is playing a leading role in this fight.

It is one of the few companies devoting enormous resources to finding a new molecule to combat TB, at its Singapore-based Novartis Institute for Tropical Diseases. It has also made available, at no profit, Coartem®, its patented combination therapy for malaria. In 2006 more than 62 million treatment courses of Coartem were delivered to more than 30 countries across Africa, helping to save an estimated 200,000 lives.

Since 2000, Novartis has been providing treatment to leprosy patients worldwide through WHO. To date, nearly four million patients globally have been offered Novartis-donated Multi Drug Therapy (MDT) free to help eliminate the disease. India, with around 65 per cent of global new case detection, is the largest beneficiary. Novartis is committed to supplying the MDT free of cost till 2010.

In 2006 alone Novartis spent about USD 755 million on research into neglected diseases and various patient-access programs, benefiting 33.6 million patients

In 2006, the Novartis Group spent about $755 million, about 2% of its revenues, on research into neglected diseases and various patient-access programs, which benefited 33.6 million patients.

As the legal process continues Novartis will maintain GIPAP in India. Patients on the program will continue to receive Glivec free of charge, for as long as they need it.

Any long-term solution for access must therefore go beyond the issue of affordability and include encouragement for innovation for the research-based pharmaceutical industry because new therapies are needed to treat different populations better, to counter drug resistance and to address new and challenging diseases of the future.

All stakeholders including government will need to come together and play a role in improving delivery systems to increase access to medicines and ensure healthcare for all.