

Access to Medicines at Affordable Prices

Dr. Y. K. Hamied



FORUM
OF FREE ENTERPRISE

Introduction

Dr. Y.K. Hamied's Bhogilal Leherchand Memorial Lecture on "**Access to Medicines at Affordable Prices**" and the documentary "**Fire In The Blood**" were real eye-openers. It demonstrated how with vision, daring and commitment corporates can tackle the numerous problems afflicting humanity, particularly the vulnerable underprivileged sections in the emerging countries.

Dr. Hamied is a true exemplar of what can be achieved by combining technological and business prowess to alleviate human suffering. As Chairman of CIPLA Ltd. he has spearheaded its growth for over three decades and pioneered the development and manufacturing of bulk drugs by utilizing indigenous raw materials, technicians and technology. He has blazed a trail by producing and marketing highly effective drugs at very affordable prices. These life saving drugs are marketed both in India and abroad at a small fraction of the price quoted by multinational companies and thus putting them within reach of those who desperately need them.

The Palliative Care Centre set up by Cipla for cancer patients in Pune, provides family care, free of cost, to terminally ill cancer patients. The Centre has given relief and solace to thousands of terminally ill patients. Cipla also has had a strong commitment

"Free Enterprise was born with man and shall survive as long as man survives".

- **A. D. Shroff**
Founder-President
Forum of Free Enterprise

to fight HIV worldwide by providing effective and affordable antiretroviral to countries in Africa, Asia and Latin America, a noble endeavor.

The documentary depicts how through manipulating and malicious practices MNCs and governments have aggressively blocked access to low-cost AIDS drugs in Africa causing millions of deaths. Dr. Hamied's valiant battle for the Indian Pharma Industry to remove the anomalies in India's patent laws has enabled Indian Pharma Industry to be globally competitive. The great stress laid by Cipla on R & D with a view to combat product obsolescence and resistance to drugs is highly commendable..

Dr. Hamied's credo that the Pharma Industry is the great health custodian of India's future generation and that life saving drugs at affordable price is a basic human right, is most admirable and worthy of emulation by others in the industry.

Cipla's odyssey is beautifully captured in the documentary, a moving narrative of exceptional accomplishment in the critical area of healthcare.

Minoo R. Shroff
President

4th December, 2013 Forum of Free Enterprise

Access to Medicines at Affordable Prices

by

Dr. Y. K. Hamied*

The world stands divided into the Rich and the Poor, Developed and Developing countries, global North with 600 million and global South with 3 billion people. In the pharma industry, we have branded drugs, branded generics and traditional generics. These distinctions are meaningless when in every country those who most desperately need medicines are those who can least afford them. Enabling access to good quality, affordable medicines is a fundamental, universal and human right. It is about preventing disease, fighting infections, easing suffering and saving lives. One third of the world's population lacks access to even basic medicines. In Asia and Africa this goes up to

* *The author is Chairman, Cipla Ltd. The text is based on the 25th Bhogilal Leherchand Memorial Lecture delivered on 12th November 2013 in Mumbai under the auspices of Forum of Free Enterprise.*

over 50%. There are 6.5 doctors for every 10,000 Indians, whereas the world's average is over 13. The right to live should not be contingent on the ability to pay. Lives cannot be sacrificed at the altar of corporate profit and greed. It is unfortunate that economic power is stronger today than moral values.

In 1972, the MNC drug companies controlled around 75% of the Indian Pharma market. Shortly after the Act was passed, most of them left India with no consideration to the health needs of millions of our countrymen. Till recently their market share had dropped to below 25% but now, they are back in force with the new Indian Patent Bill 2005 in place leading to monopoly and high prices of the newer drugs.

Let us first understand two terms that are of importance - Patents and Compulsory Licensing (CL). A patent is an exclusive right granted by a country for the manufacture and sale of a novel innovation or invention which could be a product or a process with full disclosure to enable working of the invention. It is a right to exclude others from making, using, offering for sale, selling or importing the invention for a fixed period of time, usually 20 years. This right is national, not international as each country formulates their patent laws according to its own needs.

Compulsory licensing is the term given to authorization by a government to a 3rd party to produce, market and supply an equivalent product or process without the specific consent of the patent holder. CLs are a legally recognized means of overcoming barriers in accessing affordable medicines. If a patented drug is not manufactured in the country, is unavailable or unaffordable, a CL for local production is often the only solution to assure local availability. A CL is empowered by the Patents Act to ensure that everyone benefits from an innovation and not only the innovator. It allows for generic competition, which brings down prices. What we desire is a simple pragmatic licensing system to be an integral part of our Indian Patent system to overview that the monopoly granted by a patent is not abused. Instead of the word compulsory, it may be more appropriate to say "Obligatory or Essential Drug Licensing".

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To understand IP in the context of India, it is necessary to review briefly its history after 1972.

Till 1986, our Pharma Industry flourished. We were also part of GATT (General Agreement for Trade and Tariff). During 1986-89, the developed countries led by the USA insisted that IP should be incorporated into GATT. This was vehemently opposed by many countries including India. Our Commerce Minister at that time was Dinesh Singh and he specifically instructed the Indian delegation to oppose this at a meeting called to ratify this in 1989. India very surprisingly gave in. WTO was created to replace GATT, incorporating IP and India was a party to it.

From 1989, TRIPS (Trade Related IP System) came into being. Many of you here may remember the infamous Dunkel Draft on TRIPS which was vigorously debated all over the world and at all levels in India. The matter was so serious that our government formed the I.K. Gujral Parliamentary Committee in 1993. Many of us including IDMA and myself gave evidence in parliament. After due deliberation, in December, 1993, the Gujral Committee gave their verdict and the salient points are worth repeating.

1. The Indian Patent Laws of 1972 has been rightly emphasizing patenting the process and not the product. This should be maintained.

2. The proposed extension to a 20 years period virtually discourages any R&D and should not be conceded.
3. India should insist for grant of automatic licensing in certain circumstances.

In 1995, inspite of the Gujral recommendations, reluctantly and under all kinds of pressure, India agreed to join WTO and was granted a 10 year transition period to conform to TRIPS. We were categorically told by senior bureaucrats that product patents would only come into force post 2005. Till the year 2000, nothing happened. Suddenly in December, 2000 our government introduced EMR (Exclusive Marketing Rights) which would apply to all patents filed post 1995. This was beyond all rational thinking. It is incorrect to backdate patents and WTO has no system of backdating. India was the only country to introduce EMR. In their wisdom or ignorance or whatever, our government introduced a mail-box system, whereby post 1995 patents could be deposited for subsequent review. In all 6000-7000 patents were placed.

In the year 2001, 149 countries met and unanimously finalized the DOHA declaration on 14th November 2001. This included an important clause – countries could decide for themselves as to what was a crisis in healthcare and that this should apply to TB, Malaria, HIV/AIDS and other

epidemics. At a meeting in 2003 to ratify the Doha declaration, the USA opposed the words "other epidemics" to be incorporated. It was debated and put to the vote which was 148 to 1. The USA vetoed the Doha declaration. Till today this has not been ratified.

The 10 year transition period ended in January 2005, culminating in the passing of the Indian Patent Bill in March 2005 without any debate, just a show of hands and regretfully backdating acceptance of product patents from January 1995 onwards. Only due to pressure from a few, the Bill incorporated a clause, section 3(d), to stop frivolous patenting with no real novelty and also evergreening. The government should have insisted that all patents filed post 1995 be withdrawn by the inventors if they did not comply with this clause. Unless the Patent Act is implemented in its entirety, it will ultimately deprive the poor of India and the third world, medicines they need to survive. It divides the North, 600 million people in the developed world with the South, 3 billion in the poorer nations.

I believe that we should understand the disease profile in our country. It is frightening; 110 million affected with mental illness, 80 million cardiac patients, 60 million diabetics, 60 million asthmatics, 50 million hepatitis cases, 1 in 3 Indians has latent T.B. We have a population of 1.2 billion that will

go upto 1.65 billion by 2050. Mumbai itself will be in excess of 40 million. 800 million today live with no sanitation and 500 million with no electricity. These alarming facts clearly show that we require a need based patent regime devised that utmost priority is given to secure the people's right to access affordable, quality healthcare without any monopoly. Again I repeat that this can be achieved within the broad framework of TRIPS by a pragmatic licensing policy with a suitable royalty payment to the innovator.

The achievements of the Indian Pharma industry has led to India being regarded as the Pharmacy Center of the world. Over the years, our industry has become global and we have to face global competition. India's future pharma commitments have to be global. We need to be on technological parity with the developed world. We came a long way with the 1972 Patent Act but now have been stopped in our track by the manner in which the government has implemented the 2005 Patent Bill. Our pharma industry has always been self-reliant and self-sufficient. We regard R&D as the foundation and backbone of our industry. Indian R&D will continue to innovate as best possible within the limited resources at our disposal. Pharma research is by far the most demanding of all sciences as human lives depend on this.

Product obsolescence and resistance to drugs means that innovation is never ending and newer drugs will always be forthcoming. The human mind cannot stop being inquisitive.

The key therefore to India's future progress, prosperity and success is development and innovation, incremental or otherwise. We cannot respond to the intense competition in isolation and on our own. We must expand our R&D base and build an infrastructure within India that will be the envy of all. We must all work together to ensure that essential, life saving and vital drugs are available at affordable prices, not only in the developing world but wherever needed. Our commitment today will certainly lead to future generations being benefitted. We all want an India where healthcare is provided to one and all, where every citizen can dream of a decent quality of life. We all here should be committed to this dream. Hopefully, our government will cooperate with us in this Herculean task and India will blossom into the land of our dreams.

I quote a 1981 WHO statement of Indira Gandhi, "My idea of a better ordered world is one in which medical discoveries would be free of patents and there is no profiteering from life or death".

In conclusion, I would like to highlight that to succeed one has to embrace 3 important values :

1. Vision : to anticipate, try and predict what are the key factors for progress
2. Imagination : one of the qualities that differentiates people, in particular scientists
3. Enthusiasm : the feeling that what we are pursuing in life is the one singular thing that matters.

Our industry is the healthcare custodian of India's future generations. We all strongly believe that vital and life saving medicines at affordable prices is a basic human right and that none should be denied. The overall success of a company or industry should not be judged on its balance sheet, but on its capacity and capability to discharge its moral and social obligations to society. The documentary you are going to see is factual and clearly demonstrates the power of monopoly. Hopefully, it will make us aware of what we should do, individually and collectively to give value and quality to the lives of India's future generations.

The views expressed in this booklet are not necessarily those of the Forum of Free Enterprise.

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"People must come to accept private enterprise not as a necessary evil, but as an affirmative good".

- Eugene Black
*Former President,
World Bank*

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In recent years the Forum has also been focusing on the youth with a view to developing good and well-informed citizenship. A number of youth activities including essay and elocution contests and leadership training camps are organised every year towards this goal.

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