Indian Pharmaceutical Industry - Some Myths and Few Facts

That the (Indian) Patent Act, 1970 helped the Indian Pharmaceutical Industry to emerge as a leader among developing countries is a unanimously accepted fact. This Industry has grown tremendously not only in structure but also in quality standards as well as in International trade. Inspite of the fact that the country has lagged behind in universal education and literacy, sanitation, health and nutrition, rural and women emancipation, in spite of relatively poor infrastructure, in spite of low and diminishing health allocation by the Government over the years, in spite of antiquated labour laws and militant promotional and distribution-related associations, this industry has self-propelled itself into the outer space. The Pharmaceutical Industry has contributed post 1975 immensely to improve the health parameters of Indian public. Mortality and morbidity rates have come down appreciably. Large number of rural health centres and better quality (private) hospitals and clinics are available today. Inspite of all these, the National Health Budget allocations have remained disproportionately and dismally low, while population growth has continued unabated inspite of (half-hearted) population - control policies. Consequently reach of modern allopathic system of medicine has remained restricted to 30 to 35% of India's population. This has left open wide challenging areas for future attention. With weak governance and finances, the Government may not be able to fulfill the promises made out in the 1950 Constitution, even the fundamental rights, not only of "Roti, Kapda & Makan", but also right to education and health. In line with the global trends, including the trends in Russia and China, the private sector, NGOs and private citizens will need to play an increasing role in solving these daunting problems and bridging the gap areas. Consequently, all sectors of the community will need to practice "self-help" or "self-reliance" to resolve these issues rather than look eternally to the Government to find all the remedies and solutions.

Government (both politicians and bureaucrats) used to work very closely and informally with the industry in the 60's and 70's. The atmosphere in which the deliberations for the 1970 Patent Law amendments (including the Iyengar Committee and the final round of discussions with Smt. Susheela Nayyar Committee etc.), Hathi Committee draft, the 1978 Drug Policy draft finalisations etc. were done were much more in a cordial, open-minded atmosphere charged with high degree of National spirit from all concerned. This was possible during those days, mainly due to two reasons. There was no (rampant) corruption and hence no motives could be attributed to decision-makers for sitting with Industry for deliberations. Secondly, there was more unity and fraternity among the Industry itself. Today one must admit, though grudgingly, that more damage is caused to the Industry by the spat within, rather than any force outside the Industry. Today the air of suspicion and mistrust is overwhelming like the "fog at the capital's Delhi Airport" in the winter months. This "fog" can only be cleared, if the "pollution" of corruption can be controlled or eliminated. That is another story.

What the Patent Act, 1970 did to help the Pharma Industry is well-known and visibly there to appreciate. But was there any adverse impact at all ? During the last 30 years, we in the Indian Industry, Research (including institutes) and Education (Academia) have failed to take note of the immense patenting opportunities in the developed

countries which was open for Indian Technocrats and Researchers. Even after the post-TRIPs amendments to Patent Act, 1970, for some time to come, the opportunities for Indian researchers and Industry will continue to be in the global markets. There was no reason why we should have ignored these opportunities. We could do this without compromising on National Priorities. It is indeed all the more surprising that even the other (non-food, non-drug) product segments which always had product patenting opportunities also totally ignored international patenting opportunities and even today they continue to do it.

Government policies in the last three decades are often criticized and subjected to post-mortems. They were infact relevant and useful to achieve the desired objectives (they may have been misused at times, though). Industrial Licensing may have led to excessive fragmentation of the Industry. However, the objective was to encourage competition and prevent monopolies. The incentives for small scale sector have helped a few entrepreneurs to grow into gigantic (by Indian standards) global players. The policies of import substitution, phased manufacturing programmes, ratio parameters etc have helped indeed, guide the Industry into a directed growth which was set by Government policies. The bulk drug, drug intermediate and specialty chemical industry has taken routes in India, thanks to this Governmental "carrot and stick" policy of the seventies and eighties.

The much maligned IDPL (Indian Drugs & Pharmaceuticals Ltd.) was the mother of the Indian Bulk drug industry. It still must be acknowledged at least as the "mother liquor" of the pharma-chem industry. The Hyderabad pharma industry and industrial leaders like Dr.Reddy's and others owe a lot to IDPL. Government owned Pharma companies like IDPL, Haffkine Institute, Hindustan Antibiotics in Western India and a few others in Eastern India, did make both technological and commercial contribution to the health sector. The "sickness" which largely affected the political (and to a lesser extent the bureaucracy) and the excessive interference of these powerful forces in the professional management of these organisations made them sick and redundant. There will be hardly a few in the country who might know (and remember) that the Founding Fathers of Pharma (research) service organisations like Haffkine Institute and Hindustan Antibiotics had it expressly mentioned in the Articles and objectives of these organisations that they are not intended to be profit making bodies but socio-economic health-service organisations. Someone lost the way or failed to take appropriate corrective policy decisions in time with changing times. They played their useful role in their times. Heartening that they have left behind their footprints for industry to move on which are widely acknowledged.

The current reality is that we have a vibrant domestic pharmaceutical industry which is too dear for our Nation to surrender to international pressures or arm-twisting. The least the power centres - whether they are politicians, bureaucrats, media or NGOs - can do is to leave them alone to survive in the highly competitive and aggressive global market place. However, it is extremely unfortunate that everyone of the above mentioned powers are doing their best (or their bit) to make it difficult for the domestic pharma industry in this critical times. Time and again "shock" treatments are given for imaginary reasons or huge financial demands are made just because the Government needs the

money and this is one sector which has managed to remain with its nose above troubled international waters.

How the Government is capable of killing the 'goose' that lays the golden egg (pharma industry is the most self-controlled, well-documented, straight and transparent taxpayer in the country)? Just because the pharma industry is doing its best to keep its nose above the current turbulent (economic) waters, the industry has been target of many a near-brutal tax-raids in recent times. It was too painful, at times, to see genuine law abiding friends & colleagues struggling with such "friendly" visitors.

To top it all, the ever-threatening "Damocles Sword" of DPEA could finish off a couple of well-managed pharma corporates. The best the Government could do is to forget a 25 year old aberration, an unintended damage which arose from a distorted interpretation of a provision meant to correct some imbalances between technology-deficient and technology-efficient units which needed to be brought and treated at par for pricing policy. It will be an unpardonable folly on the part of the Government to invoke this time-barred un-moral exercise. If the recent reports that DPEA is shifted to Finance Ministry are to be believed, Pharma industry can well start looking for greener pastures.

Another controversy making rounds once again is about Indian drug prices. Medicines in India are admittedly the cheapest in the world; a fact admitted by facts and figures. Most visitors coming to India from Developed Countries, carry their one year's personal needs of medicines from India including latest antibiotics. India exports medicines to most neighboring and developing countries where these medicines are sold cheaper than India, because excise duties, taxes including local taxes like octroi/entry tax on medicines are not applicable on exported medicines (under advance licence etc). Very often, wrong comparisons are made between the retail prices in India with National Formulary prices (which are wholesale & subsidized by the Government prices under National Health Schemes). If comparisons are to be made Indian retail prices of brands should be compared with prices of branded drugs in developed countries. Alternately Indian Government Tender prices could be compared with National Formulary prices abroad. It is unfair to discredit an industry working against heavy odds, by "Comparing Apples with Oranges".

I am particularly concerned and compelled to remove this myth once for all, for a very personal reason. I was recently participating in a three day international workshop in Kolkata under the aegis of "Chembiotek Research International". Large number - including top ten - multinational research groups had been participating. During and after my presentation "Destination India - Global Partnerships in Pharma Research" all other speakers and delegates (during the discussion that followed) had agreed that Indian medicine prices are often the cheapest in the world. The same evening we had the "Valedictory Session" at which the West Bengal Health Minister quoted a recent report (?) and said that Indian drug prices are the costliest in the world. All the delegates including the global MNC leaders looked quizzically at each other. During thanksgiving, Dr.Purnendu Chatterji did make an attempt to clear the confusion. I was hoping that someone will take pains to present some factual data "Comparing Comparables". I do agree that prices of all medicines are not cheaper in India. For example among one of the many dozen delegations abroad, we were confronted in

Algiers by the Government Tender Authority for our (India's) high price of Streptomycin injections. They showed us the quotes from Russia. The price quoted by them did not even cover the packing material cost of HAL and another (our bidders). This was because Russia was subsidizing (dumping) the product due to glut in their market. Once Algeria buys this item and sells in their market that item will be cheaper in their market too. Incidentally, with many Indian companies getting approval for marketing in developed countries, it is likely that products (often) could be of Indian origin which are sold at economic prices.

I have the pleasure of introducing the readers to following comparative charts to remove any doubts on Indian pharma prices. The information presented here is authentic and supporting (source) information can be provided to anyone interested.

TABLE – I : Retail Price Comparison ♦

Drug	Dose	India *	UK **	USA ***
Amoxycillin	250mg	2.75 to 4.00	8.60	7.50
Ampicillin	250mg	3.00 to 4.00	5.60	8.00
Erythromycin	250mg	4.00	9.60	11.50
Cephalexin	250mg	6.00	8.60	13.50
Propanolol	40mg	1.00 to 1.50	1.70	Not available
Atenolol	50mg	1.40	13.50	7.50
Prednisolone	10mg	10.50	0.72 (?)	7.50 (?)
Paracetamol	500mg	0.50 (strip)	0.32 (bulk)	5.00
Haloperidol	0.25mg	0.20 to 0.50 +	5.80 (5mg)	18.00
Phenobarbitone	30mg	0.40 to 0.80 +	Retai price not available (controlled drug)	Retai price not available (controlled drug)

♦ All prices are converted into Indian Rupees; £ = Rs.71/-; $ = Rs.50/-

* Prices are average of leading brands taken from MIMS India. Wherever required a range is indicated

** Prices are taken from MIMS (UK)

*** The US $ Prices are taken from the cheapest available source namely www.destinationrx.com/prescriptions (all prices are of 100's bulk pack). I am grateful to my daughter Ms.Laxmi for drawing my attention to this.

\+ wider brand based variations

? Price is for 5mg; price for 10mg not available

It is to be noted that in most other countries there is a pharmacist's dispensing charge on prescription drugs which is at times higher than the retail price of a drug. In India we get the drugs from the chemist shops at MRP or MRP plus local taxes.

A word about www.destinationrx.com/prescriptions. I got this reference, thanks to my daughter, Ms.Laxmi in USA. I found the site useful and informative. I recommend the readers to visit this site which claims to help, compare, save and learn. It is an online discount store offering 20% to 65% discounts on prescription purchases. The fact that I am using data from this site must clear me of any prejudged intentions in quoting this data.

To further support this, I quote from Government Tender price data compared with Retail Price data for same range of drugs in India. Different systems of costing are adopted in commercial practice. Most corporates use marginal costing for bulk tender supplies and are able to offer even upto 50% lower, for Government supplies, also by saving taxes and promotional expenditure (please see relevant rates for corresponding items in Table I.

TABLE – II : Tender (Formulary) Price Comparison

Drug	Dose/Packing	Indian Govt. Tender rates (in Rs.)	Source	1998 Canada in Rs. (X)	Canada in Rs. (in 2002) (XX)
Amoxycillin	250mg – Cap	0.58	Hindustan Latex Tender 15/12/2000	1.75	3.10
Ampicillin	250mg - Cap	0.84	DMER R/C 21/121999 (incl. S.T.)	1.75	2.50
Erythromycin	250mg – Tab	1.19	TNMSCL, Chennai 1999-2000	1.25	3.10
Cephalexin	250mg – Cap Cap	1.23 1.17	DGHS, N.Delhi 2000-2001 TNMSCL, Chennai 1999-2000	3.00	4.65
Propanolol	40mg – Tab	0.07	TNMSCL, Chennai 2000-2001	1.25	1.24
Atenolol	50mg – Tab	0.12	DGHS, N.Deli 2000-2001	----	12.00
Prednisolone	5mg – Tab	0.21	TNMSCL, Chennai 1999-2000	1.50	10mg strength not sold in Canada (now)
Paracetamol	500mg – Tab	0.11	TNMSCL, Chennai 1999-2000	1.25	0.90
Haloperidol	0.25mg – Tab	0.06	TNMSCL, Chennai 2000-2001	0.13	This strength is not available in Canada (now)
Phenobarbitone	30mg – Tab	0.07	TNMSCL, Chennai 2000-2001	0.25	0.31

(X) Source: British Columbia Children's Hospital Formulary, British National Formulary, No.35, March 1998, MIMS India, March 1998 (as quoted repeatedly in Pharmabiz)

(XX) Source : Glopec International, Canada – private communication of May 1st, 2002

For the sake of reader-interest, I have tried to be as accurate and truthful in this exercise. I would, however, welcome a more systematic comparative study of both retail (pharmacy) prices of prescription drugs as well as hospital formulary / Government Tender prices as a research study.

Impact of Levies - High taxes and Duties

Let me move on to high and multi-level taxes and duties in India and their impact on drugs prices. I will continue to insist that this is one major handicap India is going to face heavily vis-à-vis China. This is also one of the most important area we need to attend (a VAT system is being worked out). Most of the building blocks coming from Petrochemical units and auxiliaries like fuel, power are exorbitantly costly compared to China & other developing countries. These are facts which one cannot dispute. It is only in India that you have innumerable octrois, entry tax and other local taxes are levied on movement of goods on a very narrow region and sometimes higher than national taxes. We have been representing to the Government on this front for last 40 years with negative results. The levies have constantly gone up. New levies have come in the meantime. The best we could do now is at least seek an all-India uniformity of taxes & levies.

I also welcome the initiative from some quarters to press for a review of the duty and tax structure. I promise to work closely on this project, when undertaken.

Indian Bulk Drug Industry & Anti-dumping duties ('India Is Top Anti-Dumper') Post WTO/TRIPs, the Indian bulk drug industry went through a crisis since the mid-Nineties. With removal of Exim Policy protections and covering of Custom Duties, many inefficient and financially weaker units have wound up or changed hands (M&A). Many unviable small units have closed down.

Albeit slow initially, India has caught up mastering the Anti-dumping machinery and procedures in the last 5 years. This year India has become the top "anti-dumping" action country (Refer report dated 24th April in Financial Express and 25th April in Times of India). India has succeeded in winning maximum cases of Anti-dumping in the last two years. India has also, with expert assistance, reduced the time gap for anti-dumping action through speedy enquiry completion.

Anti-dumping duty is not a foolproof solution for safeguarding an injured domestic industry. Often it is possible to go around and manage buying from a different source or buying a lower or higher technology product of the item for which anti-dumping duty has been determined.

Many bulk drug companies have come back into black by judicious handling of finances and by innovative process development and scaling up. Many bulk drug manufacturers have either fully or partially become Contract Research and Manufacturers (CRAMs) who are GMP approved or even, USFDA/MCA/TGA certified bulk drug-intermediate-specialty chemical sources for TNCs. Extending impurity profiles to newer starting materials and newer routes, the regulatory agencies

have started extending approvals not only for bulk drugs but also for penultimate intermediates or crucial critical specialty chemicals. It is a matter of great pride that many committed and focused Indian Entrepreneurial synthetic manufacturers have successfully navigated the "rough waters" and have become "sourcing hubs" for the future. This networking with innovative process research approach is now proven to be successful and this along with cost-reduction exercises and co-operation from the Government for cost reduction alone will help this sector to steer itself into the forefront of Global Industry.

Trade Margins

As regards high trade margins, it is worthwhile to note that the New Pharmaceutical Policy or the expected DPCO (based on recommendations of committees and task forces), is expected to fix a ceiling on margins, i.e. difference between MRP and the ex-factory selling price. I agree with others that malpractices in this area need to be controlled or eliminated. On the other hand, open competition, without “order” from above, be it Government or trade association, should take care of this.

Research and Development

I am fully in agreement that in order to spur R&D activity the Government has to play a proactive role and pledge resources for such activity. Even in countries like USA, it is the NIH which takes the lead, even today, to guide and push drug research by investing in Academia, Institutes and even in Pharma Companies' research projects. In India, when the Government is not able to make or increase even the much needed "health allocation", what and how much can we expect them to do for drug research. Indian Pharma Industry has established an international presence against heavy odds. IDPL (Indian Drugs & Pharmaceuticals Ltd.) and other Government owned pharma companies, who have followed the "laudable" social objective of servicing the "unaffordable" peoples' requirements without providing for running expenses leave alone 'profits' for shareholders have bit the dust. Does any self-respecting Indian want Indian Industry to follow the example of IDPL? Every Indian must be proud that Indian Pharmaceutical Industry has established itself with its challenging presence in the International scene. With the increasing emphasis and implementation of ICH (International Code of Harmonization) guidelines and revised International cGMP (current Good Manufacturing Practices), GLP (Good Laboratory Practices) and GCP (Good Clinical Practices) etc. the capital investments and operating costs are moving up substantially. A strong R&D is a must for any Pharma Industry which wants/needs to survive. R&D expenditure in industry has to be generated from its operations. Good quality through GMP, GCP, GLP etc has also to come from sale of its products. If the pricing of a product does not provide for this, the outcome would be predictably disappointing. The Pharma Industry's future is not debatable. I do not mind loosing out on a debate. But the Industry is too dear to me to let it loose out in the current critical and challenging times.

Innovation and Patenting

It is high time that India joined the “innovation club”. Even when the Patent Act, 1970 was in operation, India could have exploited patenting Indian innovations in developed countries. We missed this opportunity due to lack of awareness and inadequate patent proficiency. Let us focus our research energies and talents into innovation. Let us support these efforts by providing necessary infrastructure in Toxicology, Pharmacology and Clinical Testing and above all “a positive mind-set”. Let us set up specialised training centres on Patenting, pharmacoeconomics, pharmacogenomics etc. and support this thrust with abundant “intellectual infrastructure”

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