Price control of patented drugs in India

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BALANCING of rights and obligations – rights of IP owners with obligation to honour needs of IP users has always been a hotspot on the IP system. TRIPs provide flexibilities for health and nutrition as in Article 7 & 8 as well as in recently amended Article 31(bis) of TRIPs, post Doha Declaration.

While costs of drug discovery and patented inventions leading to new drug approvals for NCEs/NMEs sky-rocketing due to "raising of the bar" for regulatory approval (of course arising out of new learnings from Pharmacovigilence and other reports and observations), the need to make the benefits of breakthrough in medicines and medical treatment to needy patients at affordable costs have always been a challenge, globally. Even though successive governments (Presidents & their team) in USA have been addressing this problem, including as late as 2017, the initiatives have led to a deadlock or abrupt closure, because of the powerful Big Pharma influence.

Third world countries are affected much more intensively and critically and are struggling to find ways and means of harnessing the affordable access of life saving critical medicines for their suffering millions.

Over the years, India has emerged as a global leader in generic medicines. Majority of developing and least developed countries (LDCs are looking up to India to provide solutions for critical care and life threatening diseases including serums and vaccines. While Indian pharma entrepreneurs had voluntarily set an affordable pricing program for the generic medicines, in large measures, this was led by IDPL (Indian Drugs & Pharmaceuticals Ltd.). HAL (Hindustan Antibiotics Ltd.) and other PSU pharma manufacturing units in the seventies and eighties. By overzealous enforcement of price control on PSUs by the parent Ministry and populist governments in succession, the PSU pharma units in India died a natural death. The Indian private pharma entrepreneurs had to learn and master the art of survival in spite of similar onslaughts on them. They succeeded and continues to survive because of continued entrepreneurial change of product mix, product innovation, innovative cost reduction and above all, shifting their focus to global markets.

While patients in general and senior citizens and cancer/diabetic patients in particular are happy about prices of Indian non-patented medicines, they literally start crying when prescribed a patented medicine with no affordable alternatives. I was personally surprised when I was prescribed a branded Aspirin 75mg for which the MRP was Rs.3.72 for 14 tablets in aluminium strip. This can happen only in India.

Most essential vitamin preparations in popular global brands are available in India in Rs.10 to Rs.20 for a strip of 10 to 15 tablets. Anaemia or iron deficiency is a major disease, highest prevalence in India. A patented process (process? or product by process?) of a Iron dextran complex by an MNC has successfully obtained may of Ex parte Injunctions (stay orders) from Delhi High Court against many Iron dextran intravenous injection manufacturers. The commonly available affordability prices medications for anaemia or iron deficiency will disappear with unfair monopoly to a very narrow incremental improvement over prior art in an enforced patent.

The major concern for the public is the 1 : 100 ratio in price difference between some patented medicines for cancer and critical care compared to therapeutic equivalence of generic nature with less advanced features.

This leads us to the issue of pricing of patented drugs. As an example, the government need to intervene to review the price of the iron dextran complex injection to a level existing in the market place among the generic manufacturers. This is a simple exercise for the regulatory authorities to fix the price of a patented essential dosage form. However, arriving at a policy and procedure for fixing prices of patented medicines is a much more complex exercise also brought with serious reactions and repercussions including reciprocal reprimands and counter-measures.

Other options such as more liberal VLs (Voluntary Licences) and in absence of VLs plans for more CLs (Compulsory Licences) having failed or not succeeded adequately, time and again, the government has been considering some form of price control on patented medicines.

Initiatives for price control on patented medicines

The last serious effort by the DoP (Department of Pharmaceuticals) by forming a "committee for Price Negotiation of Patented Drugs" was shot down by the NGOs who were members in the committee, on the ground that it will become difficult to grant Compulsory Licence, if prices are fixed for patented drugs on negotiated basis. However, the fact/reality is that CL (Compulsory Licence) is a dead option ever since the one and only grant of CL to (Nexavar) NATCO.

Some of the key suggestions made in the committee are as follows:

Price negotiations for government procurement and reimbursement for health insurance coverage

Based on Sec. 100 of Patent Act 1970, the Government approved agencies, handling such healthcare schemes and insurance based health packages, could be permitted to directly negotiate the prices on patented medicines under overall monitoring of the Ministry (DoP).

Price Negotiation Committee for Patented drugs (PNCPD)

The name of the committee should preferably be "Price Negotiation Committee for Patented drugs (PNCPD) or "Negotiation Committee for Pricing of Patented Drugs" (NCPPD) and not "Pricing Committee for Patented Drugs" (PCPD).

Once the price is fixed by the Government on patented drugs, alternate options for affordable access for the drugs more economically, (such as through a CL) will get closed. This is to be avoided. The options which are permissible legally, under the law of the land, should be kept open. This proposal or scheme should not impact the grant of CL (Compulsory License) for patented essential lifesaving drugs.

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"Discretion is the better part of valour"

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Reference prices in UK, Canada, France, Australia, and New Zealand in government's procurement program Could be used as reference prices but with needful adjustment based on Gross National Income, Purchasing Power Parity and Per Capita Income. The price arrived at may be designated or called the "Negotiated price" or "Price arrived at through Negotiation" and not as "Price fixed".

The prices so arrived at should not be considered as "reasonably affordable price" for purposes of CL.

Methodology of price negotiation:

A) For medicines having no therapeutic equivalence in India:

Price adjustment should consider not only Purchasing Power Parity but also Per Capita Income in ratio to those of reference price countries.

The methodology must also provide option for arriving at the domestic cost, based on inputs from research based Indian pharma industry members of the committee.

B) For medicine having a therapeutic equivalent in India:

The proposed methodology for the medicines having therapeutic equivalents in India is well-appreciated. However, the methodology of reference pricing may be adopted from (A) above. Further, indigenous cost of production in case of me-too drugs (similar to ones already produced in India by generic companies) may be ascertained or leads obtained from domestic research based pharma companies.

C) For medicines introduced first time in India itself:

For medicines introduced in India for the first time, a liberal approach with hand-holding may be adopted as developed countries do. Domestic (indigenous) Drug discoveries may also be given additional encouragements / incentives.

Efforts by the Ministry and DoP to obtain information for International Reference Pricing (IRs) system by obtaining prices from comparable countries such as China, Mexico, Brazil, Russia, Indonesia and others did not meet with success.

Timing of the discussion on pricing of patented drugs appears to be highly hazardous, considering the fact the stand of the Trump administration is unclear or confusing. Moreover, India has been ranked last but one from the bottom on GIPC's IP index ranking. USFDA has also been reportedly, reviewing their attitude to India "Discretion is the better part of valour" – Hence discretion says better discuss this on a later time frame. ◆

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