NOVARTIS PATENT CASE: A WIN-WIN SITUATION

The apex court has shown considerable insight and expertise in its judgment which finally benefitted the *aam aadmi*

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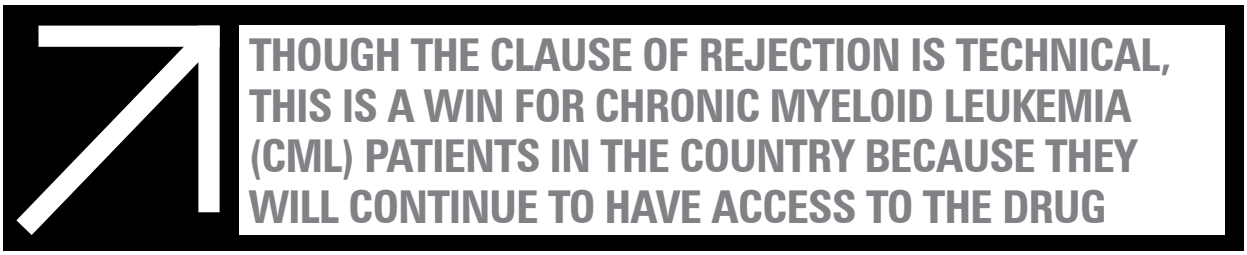
The Supreme Court's judgment in the case of Swiss pharmaceutical major Novartis' patent for the cancer-fighting drug Glivec, has aroused mixed response throughout the world. Western pharmaceutical majors see a big hit, while the Indian counter parts making the generic version of the medicine, the Cancer Patients Aid Association etc see a victory. The Apex court ruled that the active ingredient, *imatilib myselate*, did not exhibit novelty and was a known compound even before Glivec came into existence, and hence patenting was ineligible. Despite having the same drug was patented in 40 odd countries, Novartis lost its patenting plea in India on technical grounds. Novartis sold the drug at Rs. 120,000 per patient per month, While the Indian counterparts – Cipla, Natco –sold the generic version of the drug at a one-tenth price, around Rs.8000 per patient per month. As seen in the pricing, Patent (and hence the profits of pharmaceutical majors) and Access to affordable medicine are the players of the see-saw game- one up, the other down and vice-versa. The judgment recognizes and highlights the right of patients to accessible and affordable medicine over profits of organizations. While Novartis sees the same as a setback for effective treatment options that will for sure, in the long run, hinder the medical progress of a country. Also, the judgment paved the way for more caution amongst the pharmaceutical majors, who will now think twice before entering India or seeking an IP here.

Technological progress is an important indicator and contributor of economic growth. At the rate of growth in technology and competition today, companies may carve a niche position only if they recognize the importance and of R&D and invest in technology properly. For sure, such companies investing heavily in R&D and technology sustain in the market and excel others. Most pharmaceutical majors, therefore have a R&D function, which is like the back bone and a differentiator too. These companies spend a huge amount of money, time and resources in the Research & Development function for innovating and discovering new drugs to treat ailments and newer processes, the major elements being the cost of basic research, clinical trials and development expenses. For example, Dr. Reddy's invests around 10% of their turnover in R&D, Sun pharma invests around 5% of its net sales in R&D. Also certain drugs also have a R&D time as high as 12 years. For instance, as Pfizer claims, there is 1-6 years Discovery phase, 5-7 years pre-approval study phase and ½-2 year approval process. Also, 100% success is not guaranteed in every R&D trial. And we know all such costs form part of the cost of the drug directly or indirectly. R&D, being an unpredictable function, companies are more worried about their profitability and returns. Thus, having spent millions of dollars into the R&D stream, companies patent their discoveries, enjoy an exclusive branded position and try to earn a profit as a result of their industrious and laborious R&D.

Patents by large pharmaceutical companies,



hence, should not be viewed by the government or public as robbing them. Patented drugs must be priced smartly for affordable health care. However, the war between patents and price is not a question without an answer. A win-win situation is quite possible here for each of the four major players, rather pillars, in the industry – they being the Pharmaceutical Companies, the Government, the Society and the Cost & Management Accountant (CMA) for an easy and amicable going. Collaboration between all the players mentioned is highly essential for success in the right direction.

Role of pharmaceutical companies

Though the Corporate Social Responsibility keeps most pharmaceutical majors working with the patient groups in providing education and treatment to ailments, their ultimate motto is generating returns on the investments made. R&D being a function with heavy expenditure and very low success rates, companies patent their discoveries to recover the initial investment made in R&D. However, it is needed that the companies and the government act together to better sell the patented drug with a subsidy. Also, a company is sure to take a soft breath when the sales of its patented drug are routed through the government or its agencies. Such an environment encourages the companies to continue their R&D function for new drugs or ailments, as it ensures a promising return. In this way, the price can be subsidized and the affordability and availability of the drug makes everyone happy.

Most companies have a vested interest to boost their R&D expenditure as this highlights their soiled hard work in developing and innovating new drugs. Companies have to extend their co-operation and show transparency in this regard to achieve a scientific costing and pricing structure for the patented drugs. Also, most companies do not reveal the chemical names or products used in the reactions. The confidential product may be only a common salt, but its role in the reaction concerned may a new science to the world. The term 'Confidential Product' makes it more important and costly. Such costs have to be scientifically measured.

Role of government

The rejection of the Novartis patent is certainly a laudable move from the government. Though the clause of rejection is technical, this ultimately is a win for the chronic myeloid leukemia (CML) patients in the country who will continue to have access to the drug at the lowest possible cost from multiple suppliers. If patented, this would have costed around a lakh rupees a month per patient, which is now available at around ten thousand rupees a month, thereby increasing the affordability to the aam aadmi. Affordable health care, which is a social objective, to the 1.2 billion Indians is the responsibility of the government and not the business organizations. Also, the R&D function cannot be seen as a hobby of the pharmaceutical companies. Only a continuous R&D can deliver safe and effective medication, so supporting the R&D is equally a responsibility of the society. It is suggested that the government take up the R&D function, just like any other pharmaceutical company, and take patents for at least some of the essential bulk drugs and pharmaceuticals, whose price is now controlled by the Drug Price Control Order. Since generics do not creep into the market post-patent, usually for 20 years, the government can ensure subsidized price and affordable health care for its population. The government's presence and participation in the field, apart from Notifications and Orders that drive the industry with alertness, will surely bring in a healthy picture and competition in the arena.

It is also suggested that the Government to setup boards

or scrutiny entities, formed by a team of Cost and Management Accountants, which review the cost statements of the patented drugs of the companies and suggest a margin or pricing depending on the market need. A smart pricing here will surely prove beneficial to the companies, society and the government. Since R&D cost a major element in the costing and pricing of a drug, a thorough study of the R&D expenditure should be made. Also, the R&D function enjoys may tax sops and credits, the benefit of which has to be passed to the end users. This however requires transparency and trust on the part of the companies while disclosing their cost statements and confidential products or chemicals, as already mentioned.

Companies like Novartis, that have patented in multiple countries, recover the R&D expenditure manifold. A patent application in a new country will give the company an exclusive right to sell in the country. It is the government's responsibility to control the sky-rocketing price in such monopolistic situations by way of an Act or Order or the like.

Role of society

The apex court has shown considerable insight and expertise in its judgment which finally benefitted the *aam aadmi*. Access to medicine is not only limited by the patenting of drugs, but other factors like availability of health care personnel, better infrastructure for treatment and diagnosis, quality of service, poverty, health education, counterfeit drugs etc. also have a greater impact. There may a 'no' when it comes to patents and huge R&D expenditure but certainly a 'yes' when it is our own life with life-saving drugs. R&D may be an alien in the beginning but will be an acquaintance when the time comes. It is high time for the society to realize this and act accordingly.

Role of CMA

We firmly believe that the CMA fraternity has a greater role to play in the arena. The current wave of Cost Audits applicable to pharmaceutical companies already is a welcome step in this industry and is the stepping stone to success in the required direction. This however, needs a bolder beginning and step on the part of the Cost and Management Accountants and the Government so that integrity is ensured in the processes and pricing related to patented drugs especially. Apart from the Generally Acceptable Cost Accounting Principles with respect to Research & Development expenditure, a Cost Accounting Standard on R&D expenditure, will prove to be of greater help in achieving the same. As per AS-26, the accounting standard on Intangible Assets, expenditure incurred on Research is to be treated as an expense when incurred, while the expenditure on Development is to be treated as asset only if the enterprise demonstrates

a) technical feasibility and intention of completing the asset so that it will be available for use or sale
b) existence of market for the asset so generated and that there are probable future benefits
c) the availability of adequate technical, financial and other resources to complete the asset, and to use or sell it subsequently
d) its ability to measure the costs incurred for the asset reliably using its internal costing systems.

Once the development phase expenditure is treated as asset, it will have to be amortized over the useful life of the asset. However, where the enterprise cannot distinguish the research phase from the development phase in creating the intangible asset, the enterprise treats the expenditure on that project as if it were incurred in the research phase only. In the pharmaceutical industry, where the bare existence and survival of a drug in the market depends on several factors and certainty cannot be established, the companies may not risk to estimate the life of a drug and amortize the Development phase expenditure over its life. At times, a part of the expenditure may remain without amortization if the drug fails in the market even before its estimated useful life. Since R&D is a function with unpredictable swings in either direction with lower success rates, most companies prefer to charge the expense incurred to Profit & Loss Account.

Treatment of R&D expenses in certain pharmaceutical companies

Novartis charges the costs of Internal Research & Development (IR&D) to 'Research & Development' in the consolidated income statement in the period in which they are incurred. Internal development expenses of new products are capitalized as an intangible asset only if a marketing approval is obtained from a regulatory authority. Payment made to third parties for subcontracted R&D are treated as expense until it meets the criteria of internally generated intangible asset and a marketing approval has been obtained from regulatory authority. Payments made to third parties in order to in-license or acquire intellectual property rights, compounds and products (IPR&D), including initial upfront and subsequent milestone payments, are capitalized as are payments for other assets, such as technologies to be used in R&D activities. Costs for post-approval studies performed to support the continued registration of a marketed product are recognized as marketing expenses. Costs for activities that are required by regulatory authorities as a condition for obtaining marketing approval are charged as development expenses as they are incurred in cases where it is anticipated that the related product will be sold over a longer period than the activities required to be performed to obtain the marketing approval. In the rare cases where costs related to

the conditional approval need to be incurred over a period beyond that of the anticipated product sales, then the expected costs of these activities will be expensed over the shorter period of the anticipated product sales. As a result, all activities necessary as a condition to maintain a received approval, whether conditional or not, are expensed in the consolidated income statement.

Pfizer records R&D costs as expenses when incurred, including the costs incurred towards licensing arrangements. Before a compound receives regulatory approval, all costs are treated as expense. Only once a regulatory approval is received for a compound, the costs are capitalized and amortized over the expected product life cycle or the agreement term, whichever is shorter. This means an accurate measurement of product life and with certainty is quite important.

Dr. Reddy's recognizes the Research expenditure spent for gaining new scientific knowledge and understanding as expense in the Profit & Loss account when incurred. Development expenses incurred for planning or designing of new or substantially improved products or processes are capitalized only if the development costs be measured reliably, the product is technically and commercially feasible, the future economic benefits are probable and ascertainable and the company intends to and has sufficient resources to complete the development and has the ability to use or sell the asset.

Sunpharma charges all its research related expenditure to Profit & Loss account. All subsequent expenditure incurred on development is carried under 'Capital Work in Progress', as an intangible asset upon demonstration of probability of future economic benefits. In case a project does not proceed as per expectations or plans, the same is abandoned and the amount classified as development expenditure under 'Capital Work in Progress' is charged off to the profit and loss account.

However, with proper records, the cost of successful R&D may be allocated / apportioned to products on a reasonable basis and the cost will be absorbed by the product. But in case the R&D is a failure, a simple write off is done in the books of accounts. But, when it comes to the Cost Sheet, there is a need to throw light on the following with regard to CAS 13, the Cost Accounting Standard on Cost of Service Cost Centers.

The cost of production and distribution of service shall be determined based on the normal capacity or actual capacity utilization, whichever is higher and unabsorbed cost should be treated as abnormal cost. The pace of Research phase and Development phase are usually not the same. Research involves obtaining new knowledge, searching, evaluating and selecting materials, products, devices, processes, systems or services and the like, while Development involves the design, construction and testing of the chosen alternative. A faster pace means rapid cost incurrence, and when such a highly variable cost is to be determined based on capacity, there is a chance that most of it being abnormal and not being absorbed by products.

Proper accounting, allocation and apportionment of R&D costs is highly essential, especially in case of patented drugs.. We know how steeper the price variations are solely due to the presence or absence of R&D expenditure. And such a pricing has a major hit on affordability, availability and accessibility of the drug. Hence, a scientific measurability of each and every dollar spent is the need of the hour using our standards. Only a smart and scientific pricing enables to create an easy yard-stick and compare the R&D process efficiencies and efficacies too.

The role of a CMA becomes more significant and increasingly difficult as it has to honor the expectations of the three major groups above i.e., - the pharmaceutical majors, government and society. We all know that Costing function is a scientific art, and this is where we all have to prove our metal. Our decisions in costing and therefore pricing, in these situations, are very much ruling and have a direct bearing on the aam aadmi. Be it 'India Shining' or 'Bharath Nirman', we are the drivers and pace makers. Thanks to our profession, for a smart and affordable pricing is ultimately our objective.

Only then all is well.

References

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