Drug Prices - How Much is too Much?

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Received 8 July 2012

Rising healthcare costs have made drug pricing a controversial issue worldwide. ‘How much is too much’ is a question that is consistently asked in this context. While there are several factors contributing to rising drug prices, strong intellectual property (IP) laws and the efforts of private sector to monetize such IP are widely blamed for such outcome. Hence, it is important to have an open discussion on this topic to analyse whether such blame is justified. An effort is made herein to perform a concise business review to shed light on the market realities around drug pricing and the important role that a strong IP landscape plays in driving innovation, quality and sustained growth of healthcare economy.

Keywords: Drug price, drug cost, affordable drug price, compulsory license, drug development, intellectual property monetization, biopharma investment, how much is too much, greed

“Greed, for lack of a better term, is good”! These are the infamous words of the lead character Gordon Gekko (played by Michael Douglas) in the movie “Wall Street”. Over the years, Gordon Gekko’s words have been repeatedly identified with everything that is wrong with an unchecked capitalist investment system that promotes the behaviour of taking reckless financial risks with third party investments. While significant blame and outrage could be justified, the tendency in recent years (especially after the global financial collapse of 2008) has been to paint a broad-brush picture of greed and undue profits in every sector that demands large capital investment to advance new ideas to commercial reality. Biopharma sector is no exception. It is important not to lose factual financial perspective in the background noise of arguments over ideologies, political correctness and/or social inequities. In a perfect world, they all may mean well and may have good intentions. Unfortunately, as we all know, we do not live in a perfect world! Hence, the important question to ask may be “how much is too much?”

Drug prices have always been a bone of contention in both developed and developing economies. Consumers, politicians and ideological interest groups in developed nations like the US blame large drug prices as a major factor contributing to significant increases in healthcare costs. In transitional economies like India that have socialistic policy traditions that consider government as the great provider of necessary services and the regulator of pricing of essential commodities, there is tremendous pressure to control drug prices and healthcare costs. However, drug development challenges make it difficult to achieve this goal. Due to the strict regulatory landscape and the scientific risks/uncertainties inherent to this space, drug development has become a very costly proposition. According to recent data from the US FDA, less than 15% of the drugs entering human clinical studies receive final approval, with biologics having a better success rate compared to small molecules. The estimated cost of developing a drug to commercialization in the US ranges from $500 million to $1 billion.1,2,3 As the US FDA is placing increased regulatory burden for the development of drugs, it is only reasonable to assume that these costs are going to escalate. Similar is the case in Europe and Japan. Because of the ability of these markets to sustain the high cost of drugs through a combination of factors like high per capita income, reliance on insurance reimbursements and/or government payments/subsidies, biopharma companies have traditionally enjoyed very healthy returns on investment through the sale of approved drugs despite significant failures and related financial losses in their efforts to develop others.

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The venture capital industry of developed economies has played an important role in the development of new drugs by founding and funding new companies (‘start-ups’) in the biopharma space. Because of the large market potential and return of new and more effective drugs, life science investors have shown a higher degree of risk tolerance to fund translational research and development by such start-ups. In an effort to position themselves as development partners or acquisition targets for large biopharma companies to leverage resources and enhance their valuation, start-ups have played key roles in focusing on treatment areas that augment the interests of large biopharma companies and/or generate new therapeutic areas of interests for such companies. Considering the high risk of failure and the large investments required in the drug development business, these economic models have well served the investment markets of developed countries. However, the aging population, high healthcare costs and slow economic growth in these counties have sparked a debate in recent years about the legitimacy of high drug prices. Drug companies are being labeled ‘greedy’ for the prices that the public perceive to be high. The lack of a clear understanding of the drug development process and related costs play into such perception. The key question that everyone seems to be struggling with is ‘how much is too much’?

Even though the Indian regulatory environment and/or development cost base are not similar to that of US, Europe or Japan, which traditionally are the most lucrative markets for prescription drugs, there have been significant changes to the market dynamics in recent years. The days of the ‘generic drugs only’ market in India, where Indian companies manufactured inexpensive drugs, are not in the distant past. Many of them were copies of drugs that were patent protected abroad. This was possible due to a number of factors, including the (a) lack of relevant intellectual property (IP) law provisions, (b) absence of effective enforcement of IP provisions, (c) unreasonable delays in the resolution of IP disputes, (d) recognition of India’s poor IP landscape by international companies, and (e) weak position of India’s highly regulated economy and poor purchasing power of its citizens. While there were obvious price advantages to available drugs in India, the poor IP protection, awareness and economic position made several new life saving treatments unavailable to Indian patients because of the reluctance of international companies to sell proprietary products in an unprotected market. However, India is not the same anymore. It is recognized as an emerging market and a fast growing economic powerhouse. With this financial strength/power come great responsibilities. Being a part of a global economy and reaping its benefits is a team game that requires building a level playing field. By joining the World Trade Organization, India committed itself to changing its IP landscape to make it at par with the international standards. Even though this is an ongoing process requiring substantial work, IP laws, enforcement and awareness in India have significantly changed in the last decade. With stronger IP and economic environments, Indian market is poised to see more proprietary/patented drugs developed by Indian and foreign biopharma companies. Under the limited monopoly granted by patent law, it is reasonable to assume that such drug prices will reflect the cost of R&D, including investments made in failed drug development projects, to ensure returns that justify such investments. Hence, the question of ‘how much is too much’ may soon become a point of debate in India also.

The answer to this question may be in the market economics where affordability drives demand. Except in a pure socialist system, IP based goods or services are not supposed to be free. However, pricing in a market economy depends highly on whether an individual can afford such price himself and/or through a third party payer. For example, even though the average cost of a treatment course of TamiFlu, which is an anti-viral drug made by Roche, is approximately $100 in the US, the actual cost to a patient covered by a health insurance plan could be less than $20 depending on the co-pay required by his/her plan. However, if the price of TamiFlu is $1000 and if the patient’s share of payment is $200, it could affect the volumes of prescription, economics of insurance reimbursement and patient affordability. Considering the fact that every company desires to increase sale volumes to maximize market share and revenues, it is counterproductive for drug manufacturers to price it outside the affordability range. In addition, collective bargaining power that the government reimbursement agencies and/or insurance companies have from participant/customer volumes provides strong ability to negotiate for affordable pricing.
Affordable pricing may also depend on the number of patients suffering from a disease indication and the economic burden that it places on the healthcare system. In the case of rare diseases, high prices may be justified if the relevant drugs improve the quality of life and productivity of the patients and alleviate the huge economic burden that the care of such patients place on the economy. Without the ability to achieve such price points, biopharma companies and their investors will not be able to justify investing in disease indications that do not have a patient population to effectively spread the costs and generate economies of scale. Alexion Pharmaceuticals (headquartered in Connecticut, USA) sells a drug named Soliris that treats a very rare disease called Paroxysmal nocturnal hemoglobinuria (PNH). According to the National Health Service of UK, which has agreed to reimburse the price of the drug, Soliris is priced over $400,000 per patient per year. Similarly, the Australian Govt. is considering the full reimbursement for Soliris for its citizens at a price of approximately half a million US Dollars per patient per year. While these prices on their face may appear outrageous, the national health agencies of these counties have decided to or are contemplating on reimbursing such costs because of the reduction in the overall burden on the economy from the treatment of PNH and the increased productivity of such citizens. In short, if there is an efficient mechanism to effectively price drugs (ignoring any outrage over the size of such price) by performing a pure cost-benefit analysis, it could create a win-win outcome for investors and patients.

While discussing the pricing and affordability of life saving drugs, it is now practically impossible to avoid the topic of compulsory licensing, similar to the one recently secured by NATCO to make the generic version of the cancer drug developed by Bayer. The compulsory licensing provision of the WTO agreement allows government to ensure that medicines are available to patients at affordable prices. It gives the government the right to allow the sale of generic versions of patented drugs under certain conditions, including a royalty rate determined by the government, without the patent owner’s consent. Without going into a detailed analysis of the legality or legitimacy of compulsory licensing, it is important to evaluate the short-term and long term impact of such practice on innovation, innovation related businesses and quality of healthcare. As discussed earlier, drug pricing is directly related to development costs, regulatory burden, costs of doing business etc. While it may be in the national interest of countries to have low healthcare costs and drug prices, it is not realistic to expect a non-profit or money losing proposition from a for-profit company that incurs tremendous development costs to bring innovative therapeutics to market. However, it is important for governments of countries to retain the right to make certain drugs widely available at very affordable rates under circumstances where certain diseases become epidemics to threaten the foundation of their national health. The goal of the compulsory license component of the WTO agreement is to provide countries with such ability. For example, the prevalence and rate of transmission of HIV in Thailand and South Africa posed huge national health and security risks in those countries. To successfully combat this threat, it was essential for those countries to make drugs that control/treat HIV available to public at affordable prices. Hence, those countries invoked the provision of compulsory license to make HIV drugs available at such rates.

It is important that the provision of compulsory license is practiced as a rare exception and not as the general rule. If compulsory licensing provision is not used cautiously, rarely and wisely, it could lose its position of a respected essential tool, and could become a backdoor mechanism that facilitates IP piracy. India has worked hard over the years to shed the image of a country that has poor IP laws and weak mechanisms of enforcement. Respect for IP rights is very important to build a strong fabric necessary to successfully grow the business environment of any country that desires to flourish in a free enterprise system. In its absence, companies could refuse to introduce innovative and lifesaving products in the Indian market, which could have tremendous negative impact on patient care and national health. In addition, other countries could adopt lower IP standards for Indian products, which is not in the best interest of India’s efforts to build a strong life sciences economy. It is ironic that many vocal supporters of a lesser standard for the exercise of compulsory licensing may not support the application of the same principle in other business areas where perceived ‘essential commodities’ are involved. While food may be an essential commodity to the hungry, which can sustain his/her life, there is no significant support in civil society
for a mandate to force private restaurants to serve food to the hungry at a lower price determined by the government! The key question is whether there are other mechanisms, without forcing negative economic consequences on private enterprises, to achieve the same goal of making currently expensive drugs at affordable rates. Commonly used practices to this effect in many countries are government subsidies, tax breaks and cost-sharing programs. For example, both India and the US have such practices in the agricultural area to maintain the feasibility of small scale farming and to sustain affordable food prices. Such costs are usually afforded through revenue mechanisms like taxes, cost reallocations from existing programs and/or cost savings from spending cuts. It is only reasonable to assume that the same principles can be applied in the healthcare arena. It is essential that we collectively share such costs as a society without imposing undue burdens on one person/entity, stifling innovation and/or reducing access to innovative drugs/healthcare services.

**Conclusion**

It is also important to address the necessity of managing public perceptions regarding drug pricing, as drugs are considered essential commodity with direct relations to the enactment of public policy. Public policy decisions do not exist in vacuum, and hence, it is essential to be transparent about pricing strategies and their relation to investments made and returns expected. In such context, it is critical to distinguish between greed and reasonably required returns for business viability, so that there is consumer support for the desired price. The art is in the balancing act of being perceived as aggressive and not greedy in the court of public opinion.

**References**