Editorial

Are we really greedy?

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There are a dozen reasons why generic companies are perceived to be greedy by the innovator industry and by each other. These reasons currently drive our business, and we cannot act differently unless we stop and think about what we are doing, and take alternative action.

Capitalism and people drive our 2007 actions, which have changed since the 1950s when entrepreneurs in the generic industry were different. As Bill Haddad wrote in an editorial in this journal in January 2005 (volume 2, issue 2), generic company entrepreneurs with humanitarianism gained a loyal constituency that matched the money and influence of major R&D brand industry, and that breed has comfortably retired. Now we have lawyers and MBAs who defend our revenues and profit growth. In-licensing a marketing authorisation application (MAA) or an abbreviated new drug application (ANDA) now depends on numbers, not product portfolio diversification. As Bill reminded us, not one US generic company stepped forward to assist the courageous Indian generic companies that defeated the multinationals in providing drugs for treating AIDS.

The cycle of innovation drives our actions, because pharmaceutical inventors who have already been adequately rewarded want more, through life cycle management and evergreen product extension patents. They know that generic penetration into drug delivery products is a paltry 7 per cent of global pharmaceutical value. Life cycle management causes the generic industry to use counter tactics that appear to be greedy.

The current regulatory system in the USA and in Europe is applied inconsistently, and in some cases is considered to be unfair. Consider Germany, where generic firms must still pay a penalty when their branded generics (for prescriptions written by a doctor) are out of stock at the pharmacy, because the price is higher than the ceiling price. Consider the 'abuse' of Citizen Petitions in the USA where the Food and Drug Association (FDA) is unable to do anything about the average 19 months of further delay for generics due to late-filed Petitions. The generic industry has countered with a 'first-to-settle' strategy to replace 'first-to-file' to gain exclusivity in the USA, a greedy but legal practice.

The lure of authorised generics in the USA has made our complaints about the practice seem hypocritical, and therefore perceived to be greedy. Very few generic companies say 'no' when offered an authorised generic deal, but all do complain about the practice when their own drugs are impacted by the practice.

The consolidation of the generic industry breeds new millionaires, so the end game seems to be to make a lot of money instead of bringing more affordable medicines to those who need it and cannot afford it. Will generic millionaires behave like Warren Buffet did in 2006 and give it all away to help the very people who made them rich?

The internet was not around in the 1950s, and it is a new way to sell. Companies in India offer their biosimilars over the net to regulated territories at prices close to that of the biotech brand in regulated markets.

Our customers are becoming our competitors. Our wholesalers seek to own for themselves ANDAs and MAAs, using their own logistics with Indian company finished dose suppliers, thus eliminating the generic middleman altogether. One generic company retaliated by stopping the sales of all of its products to one wholesaler when it found out about the practice. One US wholesaler tried to purchase nearly 100 different Active Pharmaceutical Ingredients (APIs) from India and

found only four to be suitable in price for the US generic market at 10 per cent below best price, with the finished dosage made in China. API suppliers and their agents are perceived to be greedy by their customers, and will need to provide more reasonable pricing if they wish to stay in business.

How would we act if there were no IMS (IMS Health Inc.) data and reports to mull over? No numbers for the MBAs to crunch, nothing to drive our product portfolio selection process. Would greed be destroyed and replaced with concern for patients?

Abundant money buys political leverage, and that drives the way we behave, and is perceived to be greedy. Our industry cannot afford the vast budgets for lobbying that the innovator industry has available. We do have effective trade associations that always mention 'affordable' and 'patients' in every presentation they make. We should start doing the same.

Unenlightened Wall Street analysts blunt our courage to do the right thing for the most people, except if we are private, not subject to Wall Street scrutiny and shareholder pressure. This goes back to Capitalism, and there are very few companies like Apotex that showed the world how to deliver affordable clopidogrel to Americans, even after losing an injunction to do so. One can only wonder if such cleverness could happen if Apotex were made public and scrutinised.

Our lawyers attack patent holders to maintain our revenues and profit growth and act in our best interests. Sometimes they tell us how to act, and we take the responsibility for the greedy result.

We are who we are: limited by capital and resources, innovation in R&D of new entities cannot be done by us. We can only do what we know best, and therein is the dilemma.

But these dozen reasons are no justification for the way we should act, resulting in the perception that our actions are greedy. We must act differently and explore alternatives to do what we know best. We must reconsider timing of delivering affordable generics to those who need it, instead of maximising our profits.

Instead of pricing APIs to what the market can bear and to maximise our profits, think about mandatory price cuts in Germany, which will require constant renegotiation of floor prices. Think about how the majority of API prices prevent US wholesalers from providing generics at 10 per cent below best price. Do we really need a 300 per cent profit margin that effectively blocks affordable generics?

Instead of uselessly whining about unfairness in the USA for the creation of an abbreviated regulatory pathway for biological generics, we should not wait for legislation that may never come. Instead, we should file the Biological License Application (BLA), which has no statutory limit on the number of patients, and it is affordable to us. Since the Public Health Service Act, which established the BLA pathway, the average number of patients who were clinically tested to obtain FDA approval of the new biological entity was a startling 89. That number is affordable. Approved BLAs will not be reimbursed, just the same as NDAs, but we will deliver affordable branded generics to the elderly population growing every day in a more timely manner, rather than waiting for a less expensive route, which may never come. In Europe, we should file stand-alone MAAs on biotech drugs when it makes sense, instead of filing biosimilars when we discover comparability is impossible.

And, most of all, we should treat each other in our business with dignity and respect, strive to build relationships and trust, and we should avoid the merchant trading tactics we see in the bazaars of Istanbul and sometimes on the floor at Chemicals Pharmaceuticals Ingredients (CPhI).

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