DISRUPTIVE PRICING – THE NEW NORMAL?

Intense competition on price is something that pharmaceutical companies have always had to deal with, but this has historically been more limited to the end of the product lifecycle when generic competitors launch at substantial discounts. However, in recent years, we have seen a shift forwards in this competitive scenario, such that now even fast-followers are launching to undercut first-to-market products. So, what is driving this change? And what does it mean for pharma?

Keeping cool in Dante's inferno

Since the infamous Martin Shkreli shone a light on US pharmaceutical pricing back in 2015, the industry has struggled to reassert itself as a bastion of innovation. Such recognition is deserved: after all, it employs around 5 million people around the world, contributes a vast amount to the global economy, and improves people's lives every single day through curing and treating all manner of diseases. That Shkreli should be seen as the poster boy for an entire industry is more than unfortunate, but on focusing the public and political consciousness on drug prices, it does bring a much-needed dose of collective self-reflection and a potential re-setting of standards.

Getting a pricing strategy right for commercial success in a responsible way is a difficult task, but we certainly believe that innovation should be rewarded, and the pharmaceutical and biotech industry should receive profits to maintain that innovation, particularly in an area such as life sciences, which is already high risk and getting riskier.[1]

On the other hand, given the state of the global economy and a range of financial strains that are focused on national healthcare systems, it is understandable that there should be some concern about the rising costs of drugs. As for the super-high costs of the emerging gene and cell therapies such as Spark's Luxturna and Novartis' Kymriah, there are a variety of ways to creatively manage their introduction to achieve affordable patient access, some of which we have discussed previously.[2]

In the US, annual price hiking of already marketed products has become a common and accepted practice. However, there has been some restraint in the last few years, perhaps as a direct consequence of the Shkreli-induced reputational damage.[3] Pharma companies seem to have self-imposed a 10% maximum for increases, though not across the board. But is this increased scrutiny also having other effects on drug pricing?

Fair play is getting ever harder

One consequence of rising pricing pressures is the falling prices of generic drugs in the

US.[4] With wholesalers and pharmacies making lower profits from branded drugs and facing competitive squeezes from other middle-men like pharmacy benefit managers (PBMs), generic drug manufacturers, such as Mylan and Teva, are feeling the pinch. While some may feel this is just reward for years of over-achieving in the market when these drugs are often cheap to make, there are numerous risks associated with this trend.

> "The low-hanging fruit have all been picked and the costs of clinical development increase year on year."

Akin to cutting the circulation to a limb, too much restriction could lead to the slipping of manufacturing standards and market exit of the big players. And we know where monopolization of generic products takes us – cf. Shkreli (again). However, important as this topic is, we talk about

What about new *branded* drugs? The first observation is that, despite the spurt of recent innovation, returns on R&D investments are decreasing.[6] It is just getting harder for pharmaceutical and biotech companies to develop new drugs, as the low-hanging fruit have all been picked and the costs of clinical development increase year on year. It would be reasonable to think then that pharma's response would be to eke out every last dollar and continue to price new drugs as high as possible, and at least as much as the currently available drugs. Reasonable, yes, but not always right.

Re-thinking the price war

Typically, pharmaceutical companies want to avoid a price war, when competitive markets result in spiraling discounts as each player seeks to maintain access for their products. The revenue impact, even with maintained sales volumes, is obvious. The solution has been to price similarly and compete for volume via marketing campaigns and value differentiation strategies – see graphic below.

This mantra has served pharma well and will likely continue to do so in many cases. After all, the US is essentially a free pricing market so why should manufacturers leave money on the table (not considering the role of confidential discounts)? But, there are renegades out there who are increasingly willing to compete on price as part and parcel of value differentiation.

Let's take an example from the multiple sclerosis (MS) landscape. In 2011, Novartis priced Gilenya at about $48,000 per year – at the time, a pretty high price. Not only was it accepted, but so too were the immediate price hikes of competitor products such as Teva's Copaxone, up to about $42,300 annually.[7] Why not put the price up if they will likely lose out on market share soon enough, went the rather facile thinking.

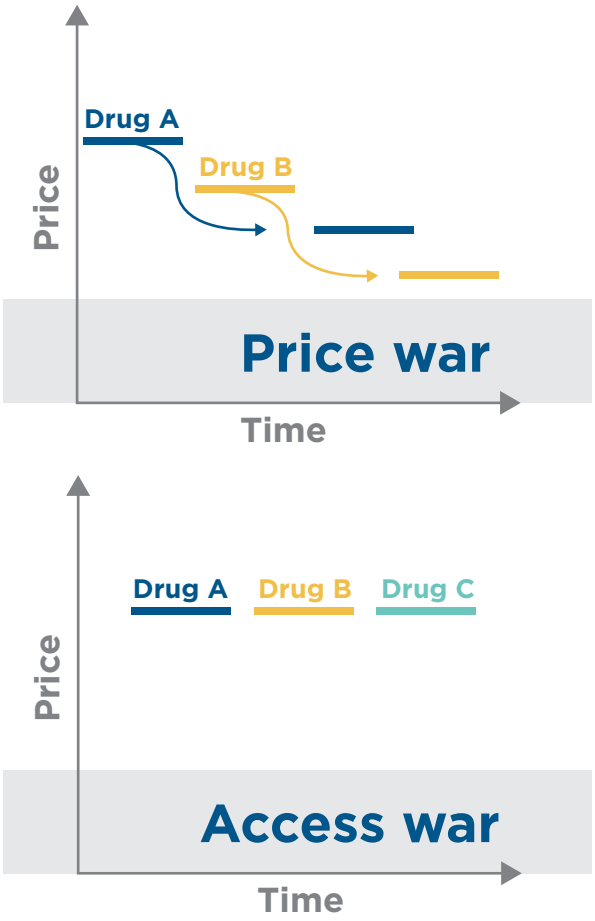
Fast-forward to 2017, and the situation is markedly different. The MS market has become more nuanced and competitive in recent years and, partly in response, Roche has set the launch price for Ocrevus at $65,000, which is 20-25% less than its comparator, Merck's Rebif, even though the former outperformed the latter in clinical trials.[8] So what's the deal?

Discounting with Strategy

This is not the only case we have tracked in the last few years, and the table on the next page shows some selected examples. A range of pharma companies have set launch prices at substantial discounts to the incumbent product, even when, as demonstrated above, the new entrant is not limited by poor clinical data, in which case price would more likely have to act as the major access lever.

Based on this data set, the discounts we have tracked start at around 20% (below this we do not consider the discount to be truly 'disruptive'), but in the case of Teva's Austedo, the discount is up to a whopping 61% compared to Valeant's Xenazine. In analyzing the above situations, there is no correlation between the price of the products and the level of discount, so there must be other more strategic factors that led to these pricing decisions. We have identified possible high-level strategic themes to the level of discount with which new entrants are coming to market. The graphic on page 4 shows three discount levels and the possible contributing factors to the strategic pricing decisions.

Exhibit 1. Pharmaceutical companies ideally want to avoid the price war situation and instead price equivalently to compete on access



Firstly, discounts of 25% and under seem to be applied to new entrants where a quick win is important for a fast-follower product to gain market share rapidly. In the case of Gilead's Yescarta, for example, Novartis had only just before set a price of $475,000 per patient. Both CAR-T products have shown superb efficacy and are gamechangers within the oncology space. But since Novartis got in the game with a little head start – and with a pay-for-performance scheme to boot – Gilead needed to react quickly or face market shutout. In settling for a moderate discount, they will at least make some payers think about awarding preferential access for Yescarta over the frontrunner. So, when a quick win is important, pharmaceutical companies should think about discounting in this range.

Examples of products discounted between 25% and 50% include Valeant's Siliq and Merck's Zepatier, in psoriasis and hepatitis C, respectively. Interestingly, both these drugs come with safety concerns that their respective incumbents do not; for the former, a black box safety warning is a definite negative and, for the latter, side effects warrant increased prescribing caution. So, how to get some uptake when the value proposition is inferior? Set a discount that will make payers stand up and fight for you, of course.

At 50% discount and above, there must be something special going on. Mustn't there? What we notice first for both products in this category is they have orphan designation. This means there are fewer patients to start with, meaning every single one counts. On the one hand, manufacturers can price high because there are recognized issues with achieving return on investment in rare diseases, but on the other, there is less time to mess around in a competitive access war. Solution: Undercut your rival immediately.

Exhibit 2. Selected competitive price scenarios ordered by level of discount (prices and discount level are undiscounted approximations)

Indication	New entrant	Annual price	Incumbent	Annual price	Discount
Huntington's	Austedo (Teva)	$60,000	Xenazine (Valeant)	$153,000	61%Huron[9]
Haemophilia A	Hemlibra (Roche)	$482,000	FEIBA (Shire)	$964,000	50%[10]
Hepatitis C	Zepatier (Merck)	$54,600	Harvoni (Gilead)	$77,500	42%[11]
Psoriasis	Siliq (Valeant)	$42,000	Cosentyx (Novartis)	$70,000	40%[12]
Ovarian cancer	Zejula (Tesaro)	$118,000	Rubraca (Clovis)	$162,000	27%[13]
PPMS	Ocrevus (Roche)	$65,000	Rebif (Merck)	$80,000	25%[8]
NHL	Yescarta (Gilead)	$373,000	Kymriah (Novartis)	$475,000	21%[14]

On top of that, these two products share another characteristic: they both have potential for wider use in a number of follow-on indications. Not only would the manufacturers hope to take some share of the currently eligible patients, but they are well positioned when expanding into other patient groups, implicitly trading near-term price for longer-term volume.

Lessons for All

The drug pricing environment, both in the US and globally, has changed and will continue to do so. While the price of differentiated products can be set freely to a degree, there are certain issues that even innovative manufacturers may want to consider before doing so.

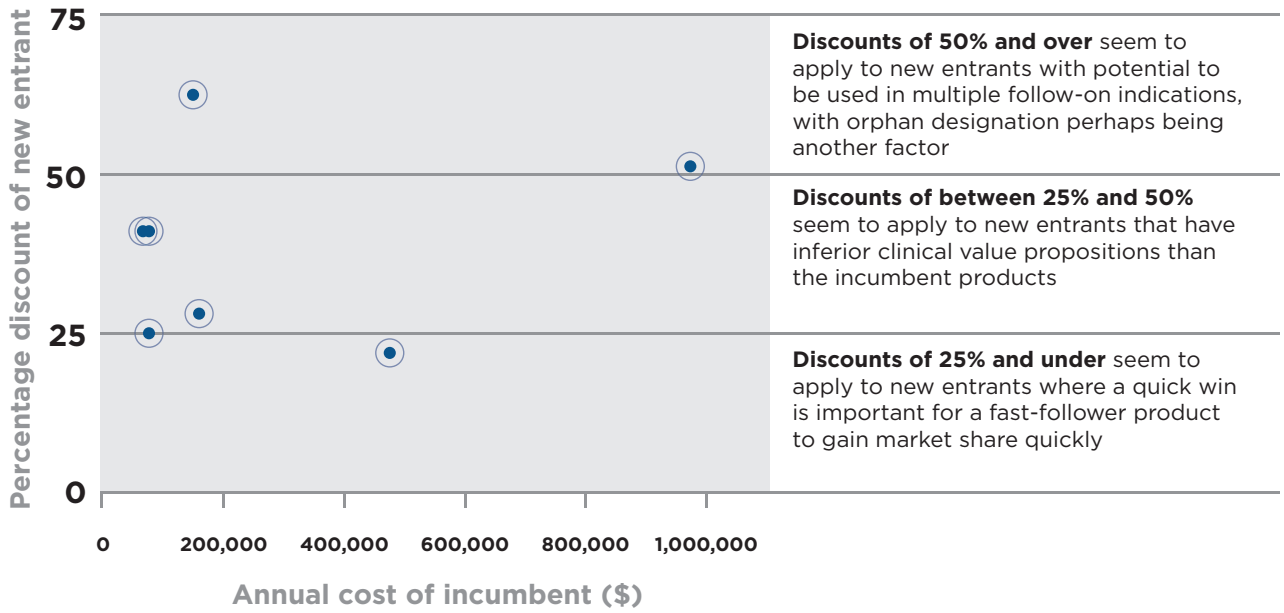
> "Preparing to encounter fast followers at substantial discount should be factored into both launch and post-launch planning"

For one thing, the speed at which rival products are entering the market is increasing, meaning that first-mover advantage does not last for long. Pricing high in anticipation of this may not be a worthwhile long-term strategy, given the potential reputational damage of being undercut by fast followers. Additionally, the risk of shutout is not just theoretical, with US formularies already closing their doors to expensive products, thereby enforcing discounting where there is competition.[15] Preparing to encounter fast followers at substantial discount should, therefore, be factored into both launch and post-launch planning.

Partly in response to the shifting price needle, fast followers are, paradoxically, beginning to lead. In fact, there is wide debate on the relative merits of being a late arrival to the party[16] and being on time (but that analysis is for another day).[17]

It is too early to validate the success of the pricing strategies outlined in this article, but through thinking about discounting strategically, manufacturers entering a therapeutic area with an incumbent already on the market can make disruption pay. Our analysis may help to guide them in their high-level thinking.

Exhibit 3. Three levels of discount set by strategic factors serve as a guide for competitive pricing



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