Some of the notable trends in the current landscape of the pharmaceutical industry bring about complex transfer pricing (TP) dilemmas that require companies to tailor their TP strategy accordingly.
Transfer pricing symptoms of chronic industry challenges

Some of the toughest challenges for you as a professional in a pharmaceutical and life sciences company come from rapidly changing market conditions and a complex global economy with multiple stakeholders. Pricing controls, the patent cliff, parallel trade, realised and unrealised firm synergies and the creation of local marketing intangibles are only some of the key areas of concern in the industry. You may deal with these issues day to day, but have you considered all their potential transfer pricing implications in today’s evolving tax environment?

Some of the notable trends in the current landscape of the pharmaceutical industry also bring about complex transfer pricing (TP) dilemmas that require companies to tailor their TP strategy accordingly.

**Pricing controls**
*Challenge: Soaring public healthcare costs*
Tighter economic governance driven by a global fiscal crisis significantly reduced industry revenues over the last few years. Constraints on budgets and healthcare expenditures will likely continue. Healthcare reforms in countries such as Portugal, Greece, and Italy are expected to reduce costs and overall pharmaceutical spending.

Pricing controls can inevitably decrease your company revenues, which are expected to be reflected in local country income tax collections. For some countries, the decrease in public healthcare costs may be tempered by a loss of tax revenues from the pharmaceutical industry.

**Why are pricing controls becoming more prevalent nowadays?**

To combat the unsustainable trend of soaring public healthcare costs, many governments have tightened pricing controls and have increased regulation of the pharmaceutical industry. These actions have contributed to an increasingly tough market. Growth economies are joining mature economies in using direct and indirect pricing controls. Russia, India, and Turkey are a few of the countries that have recently introduced new or amended pricing controls.

**TP impact: Pressure on local margins**
Government pricing controls generally impact the residual profit claimant or the local distribution entity. To insulate a local distribution entity from regulatory or pricing control risks, you may consider various alternatives,
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depending on the nature of the pricing controls. For example, you may consider decreasing the transfer price, if permitted. Pricing controls may also give you a business reason for setting up regional regulatory centres which may support your company’s strategy of centralising functions.

The interplay of regulations imposing pricing controls with TP requirements and customs regulations may create inconsistencies that can lead to conflict. While many countries do not have customs duties for pharmaceutical products, such duties are still prevalent in emerging markets, such as China, India, and Brazil. Healthcare, income tax, and customs authorities in a single country often take divergent positions on pricing issues. For example, Poland recently introduced a pharmaceutical reimbursement law that applies maximum prices

Who should bear the impact of pricing controls?
and gross margin restrictions and also limits marketing activities. Complying with the new requirements may lead to intercompany results below an arm’s length level and it is unclear whether the law overrides existing TP rules.

As a pharmaceutical company you can address the challenges of pricing controls by establishing a flexible TP system and a robust end-to-end process that accommodates the challenges of multiple tax and regulatory requirements.

**Patent cliff and post-patent life of drugs**

**Challenge: Survive the fall**

As a pharmaceutical company, you may have tasted the bitterness of the so-called ‘patent cliff’ during 2012 – when the patents for a number of blockbuster drugs expired, and sales of generics eroded industry profits. A second wave of patent expirations in 2015 is expected to shrink sales nearly as much as in 2012. These developments put pressure on research and development (R&D) in a market where sales and new product launches are expected to be limited. The anticipated result is fewer blockbusters and more high-priced specialty and orphan drugs. Patent cliff concerns are less prevalent for biologics as these large molecule drugs are more difficult to replicate.

Also, the patent cliff and the inherent pressure on the R&D pipeline may generate more merger and acquisition activity in the industry. A recent example is Amgen’s $10 billion acquisition of Onyx. Companies with promising Phase II/III drugs in their portfolio make attractive acquisition targets. More companies may also consider spinning off an established cash-generating business from a more speculative drug development business as it happened for Abbott.

**TP impact: Comprehensively redefine transfer pricing policy**

The patent cliff may spur companies to take a closer look at the value drivers of their business. In the past, many companies ascribed value to product intellectual property and manufacturing-related functions, which is most likely no longer the case after patent expiry. Therefore, companies may need to carefully consider their post-patent commercial value drivers and, if appropriate, unbundle product intellectual property, manufacturing intangibles, other corporate functions and distribution intangibles.

**How does the patent cliff impact your transfer pricing strategy?**

The distribution TP policy might have received little attention during the patented life of
blockbusters when the local market enjoyed high margins. As products come off patent and pressure on system profit increases, the local distributor should be properly compensated in line with its functional profile.

You may also want to reconsider your intellectual property licensing arrangements. Prior to patent expiration, these agreements often accounted for both product and marketing intangibles, and now their scope may need to be redefined or adjusted. Firstly you should analyse which products demand post-patent royalties and then reassess the royalty rate, which in some cases will be expected to be significantly lower.

Depending on factors such as the speed of introducing generics or certain manufacturing advantages, margins for generics can erode almost instantly or progressively over time. The resulting volatility in local distribution returns also creates challenges for local TP compliance purposes.

When patents expire, local health authorities usually like to ensure drugs reach the market at the lowest possible price (particularly if included on reimbursement lists) and could impose pricing controls that put pressure on the local distribution margin. Transfer prices should be revised immediately after patent expiration as delayed action may also have indirect tax consequences.

**Parallel trade**

**Challenge: Retain brand profit**

Globalisation has increased the challenges of retaining brand profit. An increasingly complex supply chain involving multiple stakeholders across geographies makes preventing product diversion more difficult. Therefore, one real threat to a pharmaceutical company these days is the parallel trade of drugs on the ‘grey’ market.

Parallel imports are pharmaceutical products produced under protection of a trademark or patent that are placed into circulation in one market and then imported by an unaffiliated intermediary into a second market without the authorisation of the local owner of the intellectual property right. Parallel trade occurs when one takes advantage of the price differential between two countries. For example, parallel trade tends to prevail in certain countries of the European Union (EU) where drug prices are considerably higher than in other EU member countries.

**TP impact: Manage TP audit risk**

Parallel trade products may compete with and benefit from the marketing activities of the local distributor or licensee. Therefore, your local entity sales volume
may decrease in spite of the same level of marketing efforts, which proportionally benefit the parallel importer. Tax authorities in some countries, such as Germany, are considering the TP implications of parallel trade as if local promotional activities provide a service to affiliated entities whose products get parallel exported. Local tax authorities may adjust taxpayer income to accommodate parallel trade effects by the following potential approaches:

- Deeming the parallel trade sales to be sales of the local distribution entity;
- Requiring cost-plus compensation on (deemed) local marketing and promotional expenses incurred by the local distributor with respect to the parallel trade sales; or
- Denying deductibility for tax purposes of the local marketing and promotional expenses incurred by the local distributor with respect to the parallel trade sales.

A strong brand protection programme may help you identify and prevent parallel export. You should consider a coordinated, consistent, and cross-functional approach to brand protection that reaches across the entire organisation. In assessing the related risks, you need to consider the possible impact on your TP strategy and the potential for adjustments by local taxing authorities. One option to address the parallel trade related exposures could be to have preventing compensating adjustments for the affected affiliates.
Local marketing intangibles

Challenge: Keep up with the evolving international tax environment

Tax authorities have recently looked to address the observational trend that profit resulting from locally-developed intangible property often goes untaxed in the local jurisdiction. Consequently, tax authorities are raising more and more challenges with respect to locally developed or locally funded marketing intangibles when discussing the appropriateness of characterising the local entity a routine entity.

To establish a more robust framework on the international treatment of intangible property, the Organisation for Economic Co-operation and Development (OECD) issued in July its long-awaited Action Plan regarding Base Erosion and Profit Shifting (BEPS). The Action Plan proposes 15 separate action points, including assuring that TP outcomes are in line with value creation (function) with regard to intangibles. Shortly after the Action Plan was published, the OECD released its Revised Discussion Draft on the Transfer Pricing Aspects of Intangibles. The Revised Discussion Draft provides guidance on allocating intangible-related return and focuses on functional value creation.

TP impact: Manage scrutiny of local marketing intangibles

Intensely competitive market conditions and the strict regulatory environment in the pharmaceutical industry have increased the importance of local sales and detailing activities, as well as after sale complementary activities. As such, as a pharmaceutical company you will often come under scrutiny when it comes to the risk of creating local marketing intangibles. To avoid the TP pitfalls associated with marketing intangibles, you should consider aspects of your operations that could impact this determination, such as relationships developed with local healthcare professionals and regulatory bodies, expertise of the local sales force, etc.

Local Phase IV clinical trials may also present an area of concern. Trials can be powerful tools in influencing prescribers of a product and could generate local marketing intangibles. In particular, you should consider the funding of local Phase IV clinical trials by a foreign related party to inoculate yourself of this risk.

Why local marketing intangibles are still an area of concern for pharmaceutical companies?
All these industry developments should be high on your agenda when formulating your company’s transfer pricing strategy. It is important to stay abreast of marketplace evolution and ask yourself, is my transfer pricing strategy:

1. Current?

2. Managing the needs of our various internal and external stakeholders?

3. Flexible in accommodating industry and regulatory developments?

4. Efficient and reliable?

As the industry transforms itself to adapt in a changing global economy, you are not alone in having second thoughts about some of the above questions. Crystallising your optimal transfer pricing strategy requires a clear understanding of your new operating model, deliberate consideration of several factors, lessons learned from the industry’s audit and controversy history, and a fresh perspective on the latest industry trends.

Is it time to think about revisiting your transfer pricing strategy?
Transfer pricing perspectives: Managing multiple stakeholders in the new economy

Transfer pricing symptoms of chronic industry challenges

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