PHARMACEUTICAL SECTOR

# Pharmaceutical Industry and Transfer Pricing: Anything Special?

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## 1. PHARMACEUTICAL INDUSTRY AND SOCIETY

Research-based pharmaceutical enterprises and the emerging "biotech"-coined companies uniquely have in common that they are inescapably embedded in and part of the nation states' social systems in which they are operating. The unprecedented advance of diagnostic and therapeutic solutions, in combination with the development of sophisticated instrumentation and operating procedures, have resulted in seemingly insatiable expectations of the various and, in many cultural and economic aspects, differing societies around the world.

The general expectations currently held are that for any disease or abnormal condition there ought to be a cure; that that cure is most likely to be achieved by the application of diagnostic procedures and eventually a medicine; that if no medicine is yet available for the purpose, then someone, somewhere, will discover one; and that as soon as it is discovered and proved to be safe and effective, it ought to be available to as many people as possible, as a preventative or to patients; and, where possible, it should become available free of charge.

These general expectations of the public at large and particularly the people and governments in less developed countries are to a certain extent the result of the achievements of the research-based pharmaceutical enterprises. They have been further funnelled since the deciphering of the human genome, which has accelerated the growth of biotech enterprises that promise the development of genetically engineered medicines or other genetic health interventions.

Governments, however, have more often than not failed to appeal to the personal responsibility of their people to secure and maintain their health. Such an approach would require informed patients or individuals interested in the prevention of a disease before becoming patients. Such individuals would take an interest in the environment and conditions for the provision of health care, as well as in their private health insurance coverage. This, ideally, would allow for an individual negotiation of service packages starting from the provision of basic health care (with or without a patient contribution) up to appropriate coverage for cases of potentially catastrophic events.

An informed individual taking his or her own responsibility for his or her own health seriously is surely a better solution than being dependent on governmental decisions that can effectively deny – for instance by oblivious rationing – access to appropriate medicines on the premise of national budget constraints – which is the unfortunate experience today even in some industrialized countries.[2] To entice responsible individuals to take care of their own health – without neglecting the need for solidarity with those who cannot afford to do so – is further mandated because health interventions are today, and will be more so in the future, requested not only on the basis of need but also on what is seen as fashionable.

Increasingly a grey area has been developing for the demand of medical interventions, diagnostic as well as surgical procedures, including medications that fulfil individual or societal expectations of well-being. Requesting fashionable lifestyle products that are suggested by social trends in certain parts of the society, should, however, provoke acceptance of individual responsibility. The cost associated therewith should in no way impair the provision of health care services to those in need.

## 2. NATION STATES AND THE INDUSTRY

Research-based pharmaceutical and biotech enterprises are fully dependent upon the various governmental controls of the nation states they are serving, and intend to continue to serve. Contrary to the worldwide trend of deregulation in other industries, particularly research-based and biotech enterprises are (and continue to become) the focus of various governmental agencies and their increasing efforts to implement – in some cases contradictory – regulations. Such government interventions occur at every conceivable level, beginning with the encouragement (or the lack thereof) to search for new diagnostic methods and effective therapies during the processes of research, development, manufacture, and eventual marketing of a new diagnostic or therapeutic product. Through the entire process, nation states are actively and concurrently controlling – as multiple regulators, duty and tax collectors, and also as customers – the conditions governing the strategic and operating options of the enterprises for enabling or disallowing entrepreneurship.

1. The author is an industry executive and transfer pricing expert with, amongst others, worldwide responsibility for the transfer pricing of a research-based pharmaceutical group.

2. Healthcare costs are currently heavily debated throughout the world also in relation to the demographic structures of societies together with the related expectations and the need to fund another social cost: old-age pensions. The affordability of pensions directly reverts to affordable medicines and thereby the pharmaceutical/biotech industry's inescapably being drawn into financing decisions that are regularly beyond those of other privately funded enterprises.

While the authority to regulate is clearly mandated for the assurance of safety, quality and efficacy of medical interventions, the influence of nation states on the economic parameters governing the sustainable existence of the enterprises (e.g. prices, reimbursements, costs and profits) without a clear understanding between the parties involved of the respective rules and responsibilities, creates an overall element of uncertainty and resulting business risk.

Research-based pharmaceutical and biotech enterprises are constantly torn between compassion and commerce. While these enterprises are geared to provide solutions for those who are mentally and physically suffering from (life-threatening) diseases, they have to operate on a sound financial basis, just as any other privately financed company, in order to maintain their current investors' confidence and also to encourage the engagement of potential investors.

Because of frequent misunderstandings about the modus operandi of research-based pharmaceutical and biotech enterprises and the complex net of external parameters that influence their ability for long-term and sustainable decision making, the author has provided in a separate publication for a current perspective of the ethical pharmaceutical industry and its interdependencies, especially in the area of transfer pricing.[3]

## 3. WHOSE RESPONSIBILITY IS IT?

Pharmaceutical and biotech enterprises are confronted with a lack of transparency as to the respective responsibilities of the nation states and the enterprises of the industry. While, in principle, nation states are supposed to provide for the health of their citizens, they do so with great variations. Even in the "united" market of the European Union, the principle of subsidiarity has maintained its nations' autonomous approach towards health care.

The enterprises of the industry, aiming to operate as efficient health care providers in these nation states, are, however, with moral overtones and the quest for solidarity, drawn into a blurred environment of decision making by governmental agencies, as well as various interest groups. Some of the demands may be considered part of the business model of a research-based pharmaceutical or biotech enterprise and its potentially largest customer – the nation state. Yet others, whether based on principle or in a haphazard manner, are clearly outside the business environment that any other industry would be exposed to and be required to consider also in its approach towards transfer pricing.

Concepts like solidarity, sympathy, compassion, social responsibility and particularly ethical behaviour, influence the day-to-day decision making of research-based pharmaceutical and biotech enterprises. While all of these are, and should be, governing principles of individual behaviour, the decision making for commercial transactions should also be guided by clear rules and a distinct definition of the respective parties' responsibility.

In the area of health care, it appears to be easier for governments to develop measures for controlling the supply-side, rather than to emphasize the demand-side. On the supply-side, governments control access (in some cases even after their own health authority has granted a marketing authorization), prices, volumes, costs and profits by means of requiring, amongst others, the determination of the product's "clinical excellence", the approval of pharmaco-economic (instead of health economic) studies, the demand of price reductions, paybacks, budget limitations, the enforcement of reference pricing, tiered pricing, generic substitution, parallel imports, limitations to certain levels of costs, reimbursements, and "allowable profits".

On the other hand, influencing the demand-side would require governments to create totally new structures and rules of responsibilities for the nation state's agencies, its people, the patients, and the health care providers, as well as for the enterprises of the industry and those of the trade.

In the area of health care there is an apparent lack of distinction between social and commercial responsibility. Research-based pharmaceutical and biotech enterprises clearly shoulder each type of responsibility, and the individuals working within the industry must, therefore, have a clear perspective of both. These enterprises operating as multinational groups on a worldwide basis are accustomed to regularly filing, amongst others, social responsibility reports that demonstrate their adherence to codes of good conduct particular to the industry and as good corporate citizens in the respective nation states they serve. There are the opaque zones, however, where demands for social responsibility with moral overtones of solidarity are in conflict with the commercial responsibilities that the enterprises also must respect. The lack of clarity, together with the constant moving of the goal posts by governments, impedes transparent decision making which the management of these enterprises principally is accustomed to being held accountable for.

The overriding principle governing the future existence of research-based pharmaceutical and biotech enterprises must be the ethical behaviour of their management. Although there is, of course, no claim that executives of the research-based pharmaceutical industry are a special breed of the human race, nor that the executives managing biotech enterprises have genetically coded ethics ingrained, the author is of the firm opinion that ethical behaviour evidenced through transparent systems applied and reported on a consistent basis is the indispensable survival strategy, particularly for multinational groups in the research-based and biotech industry.

They are confronted by their regular stakeholders as well as other privately or publicly organized interest groups from societies around the world with so many contentious issues that they simply cannot afford to conduct their business processes in anything but an upright, ethical and transparent manner. It is for that reason, for instance why the biotech company IDEC Pharmaceuticals (which has just announced its plan to merge with Biogen, another US

3. K. Wündisch, *International Transfer Pricing in the Ethical Pharmaceutical Industry* (Amsterdam: IBFD, 2003). This article documents mainly additional data and literature references not cited and footnoted in that publication.

biotech enterprise) states in the first line of its 2002 annual report: "Honesty, integrity and quality breed trust".[4]

As much trust is needed by patients and their physicians to rely on the safety, quality and efficacy of diagnostic and/or therapeutic products, all other stakeholders and many interest groups will want to be assured of the ethical behaviour of the enterprises and transparent systems applied on a consistent basis.

In its most recent "2003 Global 5 Hundred" report about the world's largest corporations, *Fortune* magazine devotes a special section to "Balancing Profit and Principle, Redefining Corporate Value",[5] which starts off by stating:

> When British pharmaceutical giant GlaxoSmithKline announced in April its decision to further reduce the not-for-profit prices of its HIV/AIDS medicines for the world's poorest countries by up to 47%, the move highlighted more than its long-standing strategy to improve healthcare in the developing world through preferential pricing. It demonstrates just how strong the corporate commitment is to taking a principled approach to doing business.[6]

How the effects of this and other related decisions are to be interpreted from the perspective of transfer pricing, as well as sustainability, will require considerable further analysis and also wise political leadership and judgment on both the national as well as the supranational level.

## 4. RISKS PECULIAR TO THE INDUSTRY

In addition to the overall level of uncertainty and the resultant business risk, research-based and biotech enterprises are faced with major economic, regulatory and pharma-political risks particular to the industry. Peculiar economic risks of research-based and biotech enterprises are the result of their research and development programmes being subjected to serendipity and fortuity, rather than a positive correlation between funding and the outcome of new diagnostics and/or medicines. Such risks inherent to the industry are documented by research over the last three decades which shows that investors are expected to provide the financing of some USD 900 million in order for a new medical entity to become a possibility. Even if such a new product has been secured through all pharmacological and toxicological testing and various clinical trials, enterprises marketing a new medicine may be faced with the risk resulting from unexpected side-effects to be detected only with the broader use of the product under the conditions of daily life.

In addition, and only amongst other economic risks such as the financing of continuous R&D programmes, the enterprise may be faced with no or a low return potential due to:

- the development and regulatory processes having lasted too long to be granted market access among the first entrants within a new class of products;
- the competition having already established a significant market presence;
- the marketing authorization being granted for the treatment of only a rare disease;
- a high prevalence of a particular disease in an economically underdeveloped country; and/or
- public opinion demands to provide products at "preferential", "tiered", or "equity" prices.

Various regulatory interventions provide for significant risks in research-based and biotech enterprises, as they are severely limiting their managements' ability to exercise entrepreneurship. Government interventions may preclude or limit the enterprises' opportunity to effectively utilize the marketing authorization granted, for example by

- health economic or pharmaco-economic (cost effectiveness) studies not being accepted in support of sufficient market prices;
- public or professional bodies claiming that the medicine is not of "clinical excellence" and therefore not needed;
- pricing decisions being prolonged and impaired beyond any reasonableness and/or reimbursement status not being granted;
- the additional burden of Phase IV (post-launch) and pharmaco vigilance studies,
- non-deterred parallel imports; and/or
- transfer pricing compliance programmes, i.e. the documentation burden, the uncertainties due to the use of hindsight knowledge, or secret comparables threatened to be used in audits with the exposure to double taxation, penalties and litigation.

Government intervention into the determination of market prices, reimbursement levels, or even the limitation of access to pharmaceutical products is sometimes justified by the fact that such governments are the principle customers of the industry and more and more common becomes the argument that their budgets are limited due to many other non-health but social cost-related reasons, such as the need to provide more monies for old age pensions.

In many countries, however, the cost of diagnostic and therapeutic products is only a small portion of the total cost of the health services and insufficient consideration is given to the fact that early diagnosis and treatment by medicines may be effectively cheaper in many cases than other forms of treatment (e.g. hospitalization). Instead of controlling the supply-side of pharmaceutical and biotech products, governments would be well advised to develop alternative structures for health care provision.

Research-based pharmaceutical and biotech enterprises are also faced with considerable pharma-political risks as a result of factors such as:

- an insufficient awareness and lack of appreciation for the complexities of pharmaceutical and/or biotech R&D programmes;
- the continued and sometimes suddenly changing governmental control efforts;

4. 2 *Care* 2 (March 2003), at 1. IDEC Pharmaceuticals and Biogen announced on 23 June 2003 their plan to merge (market capitalization USD 6.8 billion), and to create – after Amgen and Genentech – the third largest biotech company in the United States.
5. 148 *Fortune* 2 (21 July 2003), at 1-21.
6. Id., at 2.

– the lack of political will to allow for more competitive market forces impacting on the national structure of the provision of health care and therewith a greater transparency of respective responsibilities and accountability;
– the contentious climate surrounding the pharmaceutical and biotech industry, with the consequence of losing and/or not attracting the brightest minds as researchers for the development of needed diagnostic agents and therapeutic medicines; and
– activities of non-governmental organizations and initiatives of institutional investors that severely impact the business decisions of the enterprises.

It has to be kept in mind that such risks are shouldered by privately funded enterprises the investments of which in R&D programmes amounted to some USD 50 billion in 2002.[7]

## 5. TRANSPARENCY AND COST STRUCTURE

Transparency is needed because of the interdependencies with societal interests and the often contentious climate created as a result thereof. This is particularly so because of the often not fully understood facts and circumstances of research-based pharmaceutical and biotech enterprises. One of the thorniest issues that research-based pharmaceutical and biotech enterprises are faced with is a lack of understanding of their cost structure. To the amazement of the author, this unfortunate innocence applies not only to governments, NGOs and the media, but also to some of the consultants advising both governments and the management of the industry.

There is a significant need unmet and therefore an important task for universities to consider organizing academic training in this area. Students of various disciplines are still studying in isolation and leave their alma maters only as specialists in their own fields.

For research-based and biotech enterprises to effectively serve societies around the world, they need to attract the brightest minds whose demonstrated contributions within their own areas of academic training provide for the sought after advances. More so, however, these highly capable individuals must have an interest in and a solid grasp of the requirements and the achievements of those other disciplines with which they will have an active interface. Such an intellectual preparedness and appreciation of contributions from other disciplines are the conducive elements of an effective interdisciplinary decision making – without which highly integrated businesses would not be manageable on a worldwide basis. This is particularly true for the intricate problems that remain to be solved by pharmaceutical and biotech enterprises in the area of transfer pricing.

## 6. R&D COSTS

Vital to an understanding of the cost structure of research-based pharmaceutical enterprises is the fact that up to a third of a particular enterprise's current costs are not directly attributable to the products currently sold in a particular country. This is mainly due to the expenditures for R&D programmes which during the time frame of on average 12-14 years may or may not lead to a successful launch of a new product. Bearing in mind the impossibility of predicting the outcome of research, the high proportion of R&D activities becoming abortive, and the length of time needed for successful R&D to bear fruit in the form of a marketable product, it is prudent and widely accepted (both for statutory accounting purposes as well as by tax laws around the world) to treat current R&D expenditures as sunk cost.

Nevertheless, such R&D expenditures must be funded continuously from current revenues of all products currently sold. Because current R&D expenditures are investments for potentially positive inventions in the future, yet simultaneously funding, inherently, the many abortive programmes, these expenditures cannot in any conceivable way be directly allocated as costs to the products currently sold.

As can be observed from the experience of biotech enterprises, most of which are dependent on a positive conviction of venture capital funds to finance their ongoing R&D programmes, it is extremely difficult for a significant number of such newly created enterprises to ensure the necessary liquidity to continue their operations.

## 7. MARKETING COSTS

In order to safeguard most effectively the remaining time frame of patent protection in the various countries around the world, research-based pharmaceutical and biotech enterprises will have to launch newly developed products with initially high marketing expenditures to gain market share quickly and to establish the needed franchise which potentially would allow the continuation with sales of the products even after patent protection has lapsed. Not all pharmaceutical or biotech groups are in a position to launch a new product concurrently in a number of countries around the world. Nor would an independently operating distributor in a particular country have the thrust for such a high-impact campaign. Especially the emerging biotech enterprises often form an alliance with multinationally operating pharmaceutical groups that have the experience and infrastructure to embark on such a capital-intensive marketing strategy.

It is, however, not at all a matter solely of immense capital, but particularly a matter of professional experience with the medical profession's practice in each of those countries gained over a long period of time to conduct and control the value chain of product supply in the various countries with most differing regulatory requirements. Although the sales in most of the countries are conducted indirectly via wholesalers to pharmacists and other retail distribution outlets (e.g. hospitals), the medical profession prescribing the products is still the main target audience

7. The top 30 multinationally operating enterprises of the research-based pharmaceutical and biotech industries have together provided funding of USD 42 billion in 2002 for R&D programmes.

for the dissemination of scientific literature detailing the diagnostic or medical advance of the product in question.

In most countries this marketing effort requires a very labour intensive, face-to-face communication through scientifically educated and highly trained sales representatives. It is the experience of the research-based enterprises that they must engage in a vigorous campaign to quickly capture the attention of interested physicians, to provide them with a high quality package of scientific and medical information (and possibly also training) which together provides comfort for the acceptance of the new product.

Competition is fierce, both from other multinationally operating enterprises, as well as from indigenous national companies defending the usage of their established remedies for ailments. Therefore, to penetrate the market and to gain a sufficient market share, enterprises commonly spend on marketing (i.e. the provision of scientific and medical information, selling, and other distribution activities) between 15% and, in the initial launch period, as much as 35%, of turnover.[8]

These expenditures are at least as significant as for R&D activities in any given period. The associated risks, however, are of a different quality.

At the R&D stage, the risk is that the incurred expenditures are sunk cost and simply may not produce a marketable product at all. The efforts of the enterprises in this context may be totally unavailing regardless of how much money they spend on R&D. By the time the new product has reached the market, there is still a significant risk, but this risk is that the enterprise may not succeed in persuading its customers of the value of the new product and thus not be able to establish a satisfactory market share before other products begin to compete with it.

However, at this stage there is a product and the chances that the enterprise's marketing expenditures will make that product adequately profitable are higher than the chances at the R&D stage that any additional R&D expenditures may produce a marketable, let alone an adequately profitable product at all.

At the marketing stage the worst risk is past. The problem now is to ensure that the product succeeds. Although the current cost of doing so may in relative terms exceed even the cost of discovering and developing a new product, management is enabled to control the process of expenditure with greater stringency and with much shorter timelines to verify planned results.

## 8. PARALLEL IMPORTS

The well-intended policy of "free movement of goods and services" aims at strengthening market forces throughout an entire region, such as common markets like the European Union, the North Atlantic Free Trade Agreement (NAFTA, with the United States, Canada and Mexico), and in South America within the Mercosur.[9] This is intended to be to the benefit of the ultimate consumer, but has severely negative implications for research-based pharmaceutical and biotech enterprises.

Parallel imports are possible when the price level of a multinational group's patent-protected and branded product is lower in Country *A* than in Country *B*. Frequently this price differentiation occurs because of government price impositions in either or both of these countries. Parallel imports normally occur when a wholesaler buys products from the multinational group's subsidiary in Country *A* and there is sufficient difference between the prices in Country *A* and Country *B* for it to be worthwhile (after taking into account shipping and other costs) for the wholesaler to bring them into Country *B*. In Country *B* the wholesaler would sell to other wholesalers and/or retailers at prices less than what they would have to pay for supplies of the same product bought directly from the multinational group's subsidiary in that country.

Parallel imports have a considerable effect on the market share of sales by multinational groups of the same medicine in some northern European countries, particularly the United Kingdom and Germany. Increasingly though, also the cross-border traffic of medicines between Canada and the United States has alarmed governmental agencies, lawmakers, insurers and, especially, the (mostly elderly) public in need of continuous medication.

Economic reasoning supports the free movement of goods concept, as it ideally strengthens market forces to the benefit of the consumer. However, so far this is only evidenced by products of enterprises that are free of price controls or any other governmental interventions.

However, government-authorized activities of parallel traders endanger the return on their investments of research-based pharmaceutical and biotech enterprises. Parallel imports are a recurrent source of profits only to the non-productive trader, the no-risk taking arbitrageur.

Available evidence suggests that these imports are conducted fully at the expense of the enterprises of the originators and to a considerable extent to that of the public at large because parallel traders do not, as expected, pass their advantage on to the ultimate consumer, respectively the payer.[10] These may, ultimately, realize savings only due to the originators being forced to reduce their prices. Parallel importers have neither incentive nor obligation to forego retention of the full price differential and usually let only their sellers and buyers partially participate in their advantage.

Parallel imports not only impact negatively on the overall profitability of a multinationally operating group, they also completely distort the revenue and cost structure of the affected enterprises within the group. A group company that is based in a country with government- enforced low prices (e.g. Greece in the European Union, or Canada within NAFTA) and in which parallel imports are, or may soon be, enabled to redirect products into a higher price country, will show disproportionately higher sales compared to its cost structure. The group company's marketing expenditures have been negotiated with the originator of

8. Biotech enterprises in their initial phase of development may not have sales, and when they do (or when they have royalty income), marketing expenditures for a new product may outweigh revenues initially.
9. A common market between Argentina, Brazil, Paraguay, and Uruguay.
10. "A closer look at the savings from parallel trade", *Scrip* (18 June 2003).

the product on the basis of that country's needs. A significant diversion of products to other markets would completely distort transparent analysis efforts for equitable gross margins and therewith the negotiation of reasonable transfer prices.

Parallel imports have also become part of the emotional health policy debate resulting from the 2001-02 South African AIDS/HIV access-to-medicines crisis. In the absence of imperative action by the World Health Organization (WHO), as in cases of an epidemic, UN General Secretary, Kofi Annan, himself accepted responsibility for the global health crisis with his personal authority and that of the supranational organization he represents. Upon his initiative, the Global Fund to Fight Aids, Malaria, and Tuberculosis was created.

The initial acceptance of responsibility on a supranational level was subsequently followed by the 2002 WTO compromise formula of Doha. Apart from the Doha proposal allowing least-developed nations to demand compulsory licences for the manufacture of medicines for three diseases (HIV/AIDS, malaria and tuberculosis), responsibility was then further shifted upon pharmaceutical and biotech enterprises with the demand to apply "tiered", "differential" or "equity" pricing for their medicines to be sold in those nations. This is without any consideration for which party other than the pharmaceutical and biotech enterprises should foot the bill – and also without considering the consequences for both their pricing of products in other markets, as well as the resulting transfer pricing between enterprises within the same multinational group.

The resulting political consequences of necessary enforcement have not been sufficiently considered either. The so-called Ramsey pricing strategy (i.e. considerably reduced prices in nations with less ability to pay and/or greater elasticity of demand than in wealthy nations) requires parallel imports to be prohibited from such low-income nations. As compliance with such a mandate cannot be assured, the political debate is still ongoing, subsequent to the September 2003 WTO Ministerial Conference in Cancun, while research-based pharmaceutical and biotech enterprises continue to struggle with their decision making in that opaque zone of unclear responsibility and accountability.

Re-imports and parallel imports are the result of price discrepancies in inefficient markets. Parallel importers, as arbitrageurs, exploit these price discrepancies for as long as they exist, without being burdened by any of the risks associated with the product development, the preparation of dossiers for regulatory approval, etc. They have grown into a formidable market force by founding their own trade organization. In the words of one of its founders, "[p]arallel imports will last, as water is flowing to the lowest level, as long as prices will not have been equalized, throughout the European Union, at the lowest level".

Should governments continue to insist on their existing level of governmental interventions into privately funded businesses and at the same time allow this market inefficiency to continue, this may in Europe as well as in the United States eventually lead to the need of full government financing of medicinal research. In Europe this risk is apparent particularly in view of the ten additional states acceding to the European Union in 2004, and in the United States because of the continuing initiatives for parallel importing pharmaceutical and biotech products not only at the significantly lower Canadian prices.

The requests from NGOs for "tiered" or "equity" prices have already created negative implications beyond the discussed problems within a common market. Internationally operating traders exploit the opportunities of electronic commerce by illegally utilizing the price differential between price controlled markets.

Even the United States has not yet sufficiently geared up to the potential health hazards that may be the result of the importation of products assumed to be identical with those sold in the US market. The commercial consequences for the research-based pharmaceutical and biotech industry (and subsequently for countries around the world) of the United States allowing the import of government-enforced prices from countries without any research base, will be beyond current imagination. Private investors would withdraw from that sector altogether, venture capital would not be forthcoming, and countries would have to themselves organize and provide funding for the R&D of desired remedies for the health of their people.

However, lawmakers in fear of the electoral demands of their constituents appear to have succumbed to opportunistic and short-term decisions. Even in the United States, support for the protection of pharmaceutical and biotech enterprises that have originated the products and that have taken the risks to market them under the conditions required by the respective nation state appears to be dwindling.

> Support for a law allowing to buy American-made drugs that sell for lower prices in other countries has been rising among lawmakers anxious to address high drug prices [...]. Specifically the bill would allow the importation of prescription drugs approved by the Food and Drug Administration [FDA] and manufactured in FDA-approved plants in 25 industrialized countries. A main source of imports would likely be Canada, where many elderly Americans living near the border already travel to fill their prescriptions.[11,12]

## 9. THE ALL-OR-NOTHING IMPEDIMENT

As much as research-based pharmaceutical and biotech enterprises – in conducting their R&D programmes – are continuously confronted with the challenge of whether their original invention will live up to the expectation of becoming useful without significant side-effects, various other and comparable challenges are at stake even after having gained marketing authorization.

So far at least potential sales are created in major markets through, for instance, the positive outcome of pharmaco-economic or health economic studies, the products' regis-

11. D. McGregor, "Republican leaders face setback as drug bill gains support", *Financial Times* (27 July 2003).

12. The Pharmaceutical Market Access Act (*Gutknecht*) was passed by the House of Representatives with a bipartisan majority on 24 July 2003. To become law in the United States, it must also be approved by the Senate and signed by the President.

tration on a positive rather than a negative list, the gaining of a reimbursement status, and the support from (rather than a denial by) an access-controlling governmental agency such as the National Institute of Clinical Excellence (hereinafter: NICE) in the United Kingdom. A negative outcome of any of those challenges would, indeed, mock the entire development process, as no product sales would be the consequence.

There is no other industry subjected to such a dilemma. Assume, for instance that a thus far independently operating biotech enterprise that is relying on its ability to create an effective and safe product, negotiates a licence with a multinationally experienced marketing group to sell products on a worldwide basis. Such licence terms would usually entail advance and staggered lump-sum payments on the basis of certain milestones achieved (e.g. the ultimate marketing authorization in a particular country).

If, however, the licensee's price or reimbursement negotiations are not successfully secured or a medical supervisory body such as NICE in the United Kingdom were to hand down a decision that such a product – although it has been granted marketing authorization – should actually not be prescribed by the medical community, the licensee of the product would have to write down its lump-sum royalty payments, as the licensor would surely not be agreeable to renegotiate the licence terms.

A royalty (typically directly related to net sales) usually implies an acceptance by the licensor of the licensee's bargaining power for gaining approval to sell the product and for achieving a reasonable market price. This would determine within the given time frame of having secured marketing authorization in the various countries revenues for the licensee and thereby royalty income for the licensor. A denial, however, of reimbursement status or frankly the disapproval of the product's prescription as best practice, constitutes an absolute negation of income, irrespective of the large costs incurred in advance of the expected launch of the new product. While the licensor as the inventor should be able to rely on the franchise, expertise and negotiation intelligence of the licensee in the respective markets, it would be inconceivable (as no third party would be agreeable to renegotiate the licence terms) that the licensee would be enabled to reclaim its advances on royalties paid in case the licensee has failed to gain the support from governmental agencies for pricing, reimbursement and access.

Licence agreements usually entail in addition to initial lump-sum payments based on certain milestones, also minimum royalties on expected volumes sold during the expected life of the product. Licensors would therefore be loath to even consider granting a licence if the potential licensee would attempt to structure the royalties, including lump-sum payments conditional on the outcome of access, price, and/or reimbursement negotiations, in any particular country.

## 10. WHAT THEN IS SO SPECIAL ABOUT TRANSFER PRICING IN THE RESEARCH-BASED PHARMACEUTICAL AND BIOTECH INDUSTRY?

The basic business issue of this industry, as compared to any other industry, is the interdependence of its privately funded enterprises with the social, emotional and commercial needs of societies around the world. Such facts and circumstances may be considered as "market conditions", which surely have an effect on the transfer pricing of the enterprises.

In its guidance for applying the arm's length principle, the OECD Guidelines state: "As a general rule, these government interventions should be treated as conditions of the market in the particular country, and in the ordinary course they should be taken into account in evaluating the taxpayer's transfer price in that market".[13] However, the OECD Guidelines do acknowledge that, "[n]evertheless, it is quite obvious that a country with price controls must take into account that those price controls will affect the profits that can be realized by enterprises selling goods subject to those controls".[14]

In the author's opinion, the complexity for research-based pharmaceutical and biotech enterprises to consider all price-impacting parameters, often iteratively, to arrive at a transparent and defensible result, appears to be underestimated by many interested parties. In order to appreciate the facts and circumstances of the industry, the interdependencies with societies and their respective social systems, the resulting risks for the enterprises will have to be considered with particular care in their transfer pricing.

13. OECD Guidelines Chap. I C, 1.56.
14. Id., Chap. I C, 1.55 f. ,vii) "The effect of government policies".