Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries

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ABSTRACT

When public–sector organizations and public–private product development partnerships (PDPs) manage intellectual property (IP), they need to balance the commercial interests of private–sector manufacturers with the public sector's mission to obtain access to products at the lowest possible cost. An important tool for achieving this balance is the detailed definition of contractual milestones, which should clearly specify the terms for pricing to the public sector, territory and exclusivity, regulatory work, and time to market. Milestones should not, however, be cast in stone. Based on detailed analyses of market conditions, milestones need to remain adjustable throughout the life of the contract. When well defined, milestones can be used to ensure the availability of the most modern healthcare products to the developing world. After all, for the public sector, successful IP management is defined by how many poor people a product will reach, how easily it will be available to them, and who and how many will be able to afford the product. Accordingly, out-licensing intellectual property from public–sector-based organizations to private–sector partners requires the licensor to actively guard public–sector interests.

1. INTRODUCTION

When public–sector organizations and public–private product development partnerships (PDPs) manage intellectual property, they need to balance the commercial interests of private–sector manufacturers with the mission of the public–sector to provide access to products at the lowest possible cost. Many of the important inventions oriented toward public needs in healthcare and biotechnology result from R&D in public–sector research centers and international organizations. By adequately managing the resulting IP, the public–sector can benefit from its R&D investments by making the most modern healthcare products available to the developing world, eliminating significant barriers to access.

1.1 *The importance of contracts and milestones*

For parties entering into agreements of any kind, the primary assumption of contractual relationships is that the principal subject of their deal will be realized successfully. Obviously, this is not always a safe assumption, and when unforeseen events prevent the partners from reaching their goals, contracts differ considerably in the quality and substance of the remedies they provide. Too many contractual relations go sour because partners rush into agreements without carefully thinking about contingencies.

Without an early elaboration of contingency plans and crisis management, this honeymoon trap is why many contractual agreements contain unclear, foggy language and omit definitive, detailed, and enforceable conditions. Such conditions should address not only the contractual rights but also the obligations of each partner and the specific countermeasures to be

Oehler J. 2007. Using Milestones in Healthcare Product Licensing Deals to Ensure Access in Developing Countries. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

taken should one party run into difficulties in fulfilling its part of the deal. Instead, "best efforts clauses" or provisions for consultations to solve problems case by case are used, so as not to spoil the initial enthusiasm of making the deal. When unforseen events occur, that can be a sure recipe for disaster, especially if the mechanisms to settle disputes over differing opinions about contractual performance are unclear.

A typical contract specifies the subject matter, the duration and terms, and the rights and obligations of each party under the agreement. Licensing agreements between two organizations identify, among many issues, the nature and scope of the intellectual property or product that is being licensed, the territorial grant to the licensee where the licensed product would be made available, and the financial obligations of the licensee.

A practical example is the use of technical know-how, or the results of scientific research, that represents the particular intellectual property of a licensor and is to be licensed out to a commercial company able to create a product from the intellectual property and distribute it to consumers and users. The interests of both parties in the arrangement are straightforward and mutually advantageous—it is a win-win situation. This ordinary, idealistic assumption prevails at the beginning of any licensing deal. All too often, however, reality thwarts the goals of the initial agreement. Planned goals are missed, or forecasts wrong, and the contractual partners are left with only a subset of the original targets.

Too often, the public sector forgets that the commercial interests of private-sector companies are oriented toward maximizing profitability. Accordingly, it should not be expected that private-sector businesses will automatically provide the best services to the public sector or that they will focus on the generation and use of intellectual property to maximize public–sector benefits. To prepare for situations when the original targets of a license agreement are delayed or not achieved, and to avoid situations when projected public–sector benefits are delayed or unrealized, it is good practice to establish *contractual milestones*. These govern the goals of the license contract and set incentives for keeping to timelines and performance targets. They encourage both the licensor and licensee(s) to focus resources on their efforts to perform as initially agreed.

But milestones should not be fixed or inflexible. They need to remain adjustable throughout the lifetime of a license contract because of potential changes in project development, the market environment, and other factors that cannot be completely anticipated. When it comes to the detailed specifications of individual milestones, it does not really matter if one is choosing an absolute or a relative goal, or which definition is finally settled upon. What matters is to get the commitment of the private–sector company to recognize public–sector targets. To do this, a working set of adequate milestones should be put in place, and periods for performance assessment of the private–sector contract partner should be defined. And when new, solid evidence requires a change of rules to keep both the product and the public sector's goals alive, both parties should be open to revisions. Such results-oriented milestones require intensive preparations, detailed knowledge of the processes related to developing and marketing the product, realistic forecasting of product potential, persistence in quantitative forecasting and establishing a master plan for the entire product roll-out, and a mission-driven mindset to establish optimum goals for the public sector.

Additionally, it is useful to spell out the level and conditions of fines (monetary or otherwise) to be paid when a partner does not fulfill its obligations. This should include a mechanism to prevent prolonged periods of quarreling over differing opinions and disagreements over performance. Otherwise, product development or marketing efforts could cease, which would ultimately hurt the public sector.

Most milestones cover:

- pricing to the public sector
- territory and exclusivity
- regulatory work and time-to-market
- royalties
- terms and termination of the license agreement

1.2 *Public–private partnerships: closing the medicines access gap in developing countries*

The role of ***public–private partnerships*** (PPPs), or, in the context of health, more and more frequently public-private product development partnerships (PDPs), as an innovative approach to the discovery, development, and distribution of health products, drugs, and vaccines for developing countries has been emphasized repeatedly in various publications. In fact, more than 90 PPPs have been established worldwide.[1] However, the accomplishments of PPPs/PDPs are rarely publicized, partly because most of these entities are relatively young. Half of these partnerships have been established since 1999. Since normal times to market range from no less than ten to around 12–15 years, on average, in a pharmaceutical R&D or healthcare environment, the time in existense of these partnerships has been relatively short. It is still possible to begin to gauge, however, the success of these ventures.

One example of a PDP is the Concept Foundation,[2] established in 1989 through the initiative and funding of the World Health Organization's Special Programme of Research, Development, and Research Training in Human Reproduction (WHO/HRP), the World Bank, and United Nations Population Fund (UNFPA), PATH/PIACT,[3] and The Rockefeller Foundation. The mission is "*to provide access to top quality reproductive-health products for developing countries at lowest possible prices in order to realize maximum public-sector benefits through the management of intellectual property and technology transfer for contraceptives and pharmaceuticals that otherwise would not be available to the public sector with the intended quality and prices.*" The Concept Foundation has accumulated extensive experience managing health technologies development and technology transfer in the pursuit of rolling out new technologies in the developing world.

Successful PPPs/PDPs are built on value propositions, from the public sector to the private sector, that take advantage of the inherent capabilities of the former. The public-sector IP manager should identify the capabilities that are relevant to a particular public–private partnership and turn these capabilities into specific value propositions that will help the private–sector partner realize its commercial goals. No potential benefit to the public sector, however, should be sacrificed. In this context, it is especially important to overcome the common phenomenon of further *marginalizing the poor* in the small and smallest countries of the developing world. Market attractiveness governs priorities in a commercial environment, but in a public–sector context, the poor in the smallest countries have the highest needs for accessing affordable products. As the experiences of the Concept Foundation reveal, the public sector successfully manages its intellectual property when it bridges these ostensibly opposing interests.

The R&D process for developing new drugs, vaccines, and diagnostics for diseases that afflict the poor is a crucial step toward ultimately eradicating these diseases. Many PPPs/PDPs concentrate their efforts on product development, and the largest product-development PPPs/PDPs have successfully raised (in combined figures) more than half a billion U.S. dollars in recent years to fund their R&D efforts. However, product delivery is an equally important, if not more decisive, factor for access to medicines, and most product-development PPPs/PDPs are not working to ensure that their products can be delivered to the local healthcare infrastructure. Indeed, product-development PPPs/PDPs have little experience with the downstream issues involved in bringing products to such markets.

But PPPs/PDPs face numerous downstream concerns associated with handling and financing the introduction and launch of new products including:

- adequacy of healthcare infrastructure
- disease surveillance
- compliance monitoring
- education and training of health workers and medical staff
- improving healthcare facilities
- physical distribution networks
- satisfactory supply volumes

- adequate volume forecasting
- minimizing product waste at the point of treatment

As is well known from experiences in the pharmaceutical industry, successful marketing and distribution of a new medicine is a significant, decisive part of its cost structure. While nobody would expect the need to create market demand (in other words, investing marketing dollars) for products to fight diseases of poverty (these markets exist!), huge investments are needed to compensate for the inability of the poorest regions to pay for both modern, effective products and for all downstream tasks related to effectively supplying and distributing these medicines. In addition, costs for surveillance programs to guarantee successful outreach to all who need treatment must be included. Product development public–private partnerships lack the experiences to address these downstream issues.

These efforts must include achieving the lowest possible manufacturing costs so that preferential pricing can be provided to public health services, establishing sustainable manufacturing with a continuous system for monitoring quality, and creating a business model that is financially attractive to private pharmaceutical companies thereby overcoming the expected poor returns of operating in public sector markets. The PPP/PDP business model of the Concept Foundation has helped to realize these goals. It takes into account the downstream issues surrounding product delivery and successfully utilizes contractual milestones to achieve the principal goal of closing the medical-product access gap in developing countries.

2. THE GREAT DIVIDE IN BUSINESS MODELS: INDUSTRY AND THE PUBLIC SECTOR

No matter how well public sector players think they understand industry, the discussion between the public sector and industry is a cross-cultural event. In such a cross-cultural environment, there is nothing more dangerous and conducive to misunderstandings than to *assume the obvious*, since what is obvious for a person with a public sector background may be different for a potential partner. Do not leave obligations and contractual performance to best efforts and common sense! It is much better for both partners to specify in writing exactly what the public sector wants to achieve with a commercial partner. The document should detail exactly when and how the objective will be achieved and specify penalties for failure to meet objectives. If the agreement specifies only best efforts and unspecified performance, disaster threatens!

To manage intellectual property for maximized benefits to the public sector, the expectations of the public sector to obtain products at the lowest possible prices, with excellent quality, and in sufficient quantities must be balanced with the expectations of private sector companies to generate a satisfactory rate of return.

Important value propositions for pharmaceutical companies are:

- **Save time to market.** An earlier market entry means higher market share opportunities for the company and, ultimately, more sales. Example: Pharmaceutical or clinical research, using an existing network of public sector institutions in parallel speeds the generation of results needed for drug regulatory approval by saving the lead time required to approach new, unfamiliar trial sites and train in GCP (good clinical practices).
- **Save resources.** Reduced need for internal company resources means a lower cost burden for the licensee and improves the bottom line. On the other hand, when investment levels are maintained, more parallel activities are possible with the same amount of resources, helping to increase the company's commercial output. Example: Existing public sector distribution networks, formal or informal, allow a product to reach a large public sector market very quickly without the costly build-up of a supply chain.
- **Save investments**. A reduced need for investments means better cash flow

utilization within the company, which is very important for investors.

Any plan for a value proposition must deal specifically with the nature of the partnership, and a successful proposal must present an authentic and actual value to a potential partner. These authentic, actual values must be based on the set of capabilities that the public sector organization can offer—this is precisely the platform for the creation of value—and based on what private sector partner needs could be met by the public sector. Such genuine values include the examples above: save time to market, save resources, and save investments. As these demonstrate, one must look behind the immediate and apparent face value of individual capabilities in the public sector to be able to identify and compose the true value of such contributions. Indeed, an authentic value proposition is more often composed of several contributions from various capabilities than a single value factor.

Understanding all the specific values when just beginning to approach potential licensing partners is essential—especially those values that drive an industry and are particularly important for the potential licensee. A detailed analysis of these values and their alignment with existing public sector capabilities helps to identify the value propositions that public sector organizations can offer their private sector partners.

3. THE MOST IMPORTANT MILESTONES

Maximizing public sector benefits through IP management has three key aspects:

1. definition of the geographic coverage for marketing the product (that is, territory)
2. the claim for product exclusivity by the private sector licensee
3. the definition of the preferred public sector price or other public sector benefit

These may seem very straightforward. It is easy to imagine that the partners in a license arrangement would agree on a set price for the product for public sector distribution, agree on the countries in which the product could be sold and that, as a result, the private sector company, as licensee, obtains the exclusive rights to marketing and sales of the product in this territory. However, in real life, this does not necessarily mean that public sector benefits have been maximized. Some key questions need to be answered:

- How well will we reach smaller countries with our product?
- How well will we reach rural populations in developing countries that normally remain underserved?
- Who will benefit from obtaining the product at a special public sector price?
- How can we ensure that we will obtain the product at prices affordable to public sector agencies?

The principal way to address these issues is to set contractual milestones that prevent the marginalization of the poor in smaller countries, regulate public sector access, and set the geographic coverage for all countries in a territory (even in countries and regions that are not interesting enough to generate sizeable returns on investments and would therefore normally not be served). Finally, there must be a clear framework for computing manufacturing costs, and this cost calculation must be available to the public sector partner.

Due to commercial pressures, putting the private sector and its commercial interests before those of the public sector is an inherent danger. Such prioritizing usually reflects attempts to simplify the private sector partner's participation because of fears about failing to make a deal. While simplifying agreements is good practice, establishing specific contractual milestones and clarifying them under the terms of an agreement are not necessarily complications. Success requires focusing on which areas to target and which issues to exclude. A tight focus will guarantee the simplicity of the provisions and regulations without overburdening an agreement.

When it comes to public sector benefits, simply making a product available at market prices or quickly placing it on the market does

not indicate progress. Success is instead defined by how many poor people the product will reach, how easily it will be available to them, and who and how many will be able to afford the product. The goal is to reduce morbidity and mortality. For the public sector, this is the ultimate aim of product development. The necessary achievements for obtaining this outcome need to be clearly specified as milestones in an agreement. We will next take a closer look at territory, exclusivity, and pricing.

3.1 *Territory and field-of-use*

A typical license agreement will specify the grant of the license. Language such as: "*LICENSOR grants COMPANY the rights to manufacture and sell the PRODUCT into the PRIVATE SECTOR and PUBLIC SECTOR markets of the TERRITORY*" is commonly used. The terms *LICENSOR, COMPANY, PRODUCT, PRIVATE SECTOR, PUBLIC SECTOR*, and *TERRITORY* are used according to the definitions in the introductory "Whereas" chapter to the agreement.[4]

Under this wording, the license grant is established as a right of the licensee to the product. However, the license grant does not specify the obligation to sell into the territory. This is a very important issue of practical IP management for public sector benefits. While it is reasonable to assume in the case of a one-product, home market manufacturer that the licensee will introduce the product into this (single) market, it is not necessarily true that a licensee will introduce the product into all markets of a multicountry territory, especially the public sector. This failure to reach all the desired markets may result from various factors that were not known or were underestimated when the license agreement was established.

Between the signing of a license agreement and the commercial roll-out of the product, a considerable period of time may be needed for product development, manufacturing scale-up, and regulatory approval. Depending on the capabilities of the licensee, this time period may well extend over several years. During this time, the company's business and the business environment may change significantly, and resources that originally were available for dealing with the product may have been partially redirected to other, possibly more profitable, products and projects. Markets that initially seemed attractive may have lost their appeal compared to other opportunities since recognized by the company.

Changes in the business environment and the focus of the business may affect the licensee's commitment to serve the public sector as originally envisioned for the entire area. To ensure availability and access to the product in the public sector's territory, it is only prudent to use the license grant to obligate the licensee to sell the product in that area—not just as a right of the licensee. This can be accomplished in various ways:

- By separating the grant of the *rights to manufacture the product* from the *obligation to sell the product into all countries of the territory* (Emphasis here should be on *all countries* in the territory.)
- By attaching milestones to the execution of the sales rights for the product (Only after showing defined success according to the milestones would the licensee be granted additional sales rights for other countries.)
- The rights of the public and private sector to sell the product could be dealt with in separate regulations that prioritize the public sector organization's goal of introducing the product into the public sector at a satisfactory level (to be defined by an adequate milestone) in one country, before additional rights to markets—public and private—in other countries would be granted. The license grant could specify, for example, the rights of a Brazilian manufacturer to produce and sell the product in Brazil, the home market, and the rights to sell it in other Latin American countries, once certain conditions are met. A wide range of options for these conditions are available and could be specified in the license agreement, such as:
  - **Market share.** licensee will gain the rights to sell into other countries after

establishing a market share of 20% in the specific market segment, as reported by IMS.[5]

- **Market position.** licensee will gain the rights to sell into other countries after positioning the product among the top-three products within its category in the Brazilian market, as measured by analyst reports.
- **Sales volume.** licensee will gain the rights to sell into other countries after an annual sales volume of five million units is realized in the Brazilian market, as measured by cumulative sales reports from distribution agents.
- **Public sector penetration.** licensee will gain the rights to sell into other countries after the total output/annual output into the public sector in Brazil has reached ten million units, as measured by procurement orders from public sector agencies.

In addition to the milestones for gaining the rights to sell in additional countries, the remaining countries in the licensed territory could be prioritized in order of importance for the licensee, and eventually the licensor as well. Each country on the list would then be characterized by individual milestones that the company must reach before it could sell in an additional country. These country priorities and milestone definitions should be set when signing the license agreement, with the option to revise the priorities and milestones after a certain period.

It is unwise to leave country priorities or milestone definitions open and uncovered for the sake of higher flexibility (for example, setting the next country priority shortly before reaching the last defined milestone in the actual country of activity or a similarly flexible model that postpones decision-making). Reaching consensus about country priorities and milestone definitions might become more and more difficult for the licensor and licensee, especially the closer the country of choice is to the bottom of the priority list. The licensee might then no longer desire to sell in a particular country, and especially to the public sector, due to various, possibly hidden, reasons. The company could walk away from its responsibilities to serve a particular country. In this case, the private sector company would not be violating the license agreement, since the milestones had not already been mutually defined and negotiations about new milestones had failed.

On the other hand, priorities and milestone definitions may change over time in a fast-moving business environment. Indeed, they might not be considered valid after several years into the lifetime of a license agreement. This is a common concern when it comes to defining priorities and milestones, especially among advocates of real-time implementation. Given the need to eventually define priorities and milestones, to protect public sector access to the product everywhere as far as possible, and to avoid the inherent dangers of leaving important parts of an agreement initially undefined pending a later mutual understanding, it is close to irresponsible to skip over these definitions and omit them from the initial version of the signed license agreement. One can provide for a regular update of the details of these conditions, when a changed environment requires them, for example, by calls for revisions. At that time, however, it would be up to the licensee to demonstrate the need for changes and to prepare a detailed proposal of what to change and how to change it. Unless the proposed changes bring up compelling reasons for the licensor, original priorities and milestones would prevail. The originally defined public sector goals would remain in force without alteration and the licensee would still be required to honor these goals.

Initially defining contractual priorities and detailed milestones is, of course, a painstaking process that requires intensive preparations to ensure that essential aspects of the public sector's objectives are not overlooked. This desk research and information collection is essential for adequately preparing license agreements that serve public sector interests. For initial negotiations between parties, the terms of a licensing agreement should be rolled-out in all related details, even though it may be difficult and

resource-intensive to formulate all of them. The tendency to postpone detailing specifications, or calls from the contract partner to omit the necessary detail in order to simplify and quickly reach an agreement is a trap. It does not allow the parties to establish the necessary framework for an efficient and effective public sector-oriented licensing arrangement. If it is impossible to reach an agreement on staggered priorities with detailed milestones in the beginning of the contract relationship, how can these differences be ironed out later?

3.2 *Exclusivity*

One of the first things that companies ask for is exclusivity. It is important to link such requests with specific milestones, such as:

- volume of sales reached in certain markets after a certain time period from launch or from the signing of the agreement
- level of market share reached against competition
- level of market share established in a new market segment, measured against the total product potential
- level of coverage of different regions in a large market or across different countries of a region
- latest product launch date into a market that will secure product/technology exclusivity for the company, in general, for a selected territory

Specifying penalties and fines for the licensee if these milestones are not reached is just as important as setting the specific milestones. The penalties could be:

- temporary increase of royalties on private sector sales until the milestone condition has been reached
- loss of exclusivity for the product or technology and conversion to a nonexclusive license, in general, or for a specific region
- loss of exclusivity and territory to a competitor
- payment of a fine, in a predefined amount, for failure to introduce a product into a country under exclusivity for the licensee.

It is good practice to evaluate the request for exclusivity with respect to the public sector benefits that a potential licensee could deliver. Again, it is unreasonable to expect that a private sector company would concentrate major resources on serving the public sector when there are no specific obligations in the license agreement or milestones are inadequate or undefined. Since the request for exclusivity is made to protect the commercial potential of a market place, the public-sector partner has the right in a quid pro quo to ensure the protection of public-sector needs. It is especially important for the public sector partner to understand what kind of resources—in terms of quality and quantity—the private sector company will make available and mobilize for the public sector segment of the exclusive territory. This understanding should be clearly stated in the license agreement.

3.3 *Pricing for the public sector*

A key issue for the public sector in developing countries is product affordability. Prices must ensure the widest possible availability. Prices, however, are calculated differently in the pharmaceutical industry than in the public sector.

Pharmaceutical companies commonly use a retrograde calculation scheme. They base product prices on the perceived purchasing power of the target segment in a market. Manufacturing costs are not a major factor for the price calculation. Overhead and marketing costs are usually higher than production costs and need to be well offset by product pricing. To a large extent, adequate product positioning into affluent markets determines achievable margins and operating profitability.

In contrast, the public sector mostly uses the cost-plus model for price determination. Manufacturing and organizational infrastructure contribute significantly to costs. Sales and marketing costs are kept at the lowest possible levels so as not to increase the product's price. A reasonable, but small, rate of operating profit is added on top of these costs to determine the product price. With the purchasing power of the public sector under severe limitations, a price

determination along the lines of a cost-plus model is the method of choice.

An effective license agreement needs to employ a detailed cost-calculation model. Its aim should be to understand all directly and indirectly attributed product costs that contribute to final cost. By applying the model and marking up the ex-factory product price with a mutually accepted profit margin for sales into the public sector, a reasonable platform for determining the lowest possible public sector price can be achieved. For indirect costs, it is necessary to find out if the cost burden on the product is fairly allocated. In the end, of course, private sector pricing of the product is entirely up to the discretion of the manufacturer and not a public sector concern.

It is good practice to mandate the annual submission of manufacturing cost reports and product cost-calculation details. Furthermore, the licensor should reserve the right to have these cost reports independently audited.

Should a manufacturer be unable to match expected price levels for the public sector when the company begins manufacturing, a definite timeline should be set to reach those levels. Adequate penalties should be in place to cover such cases. While a license agreement cannot be a tool to force a manufacturer to sell a product below cost, a detailed agreement based on the manufacturing cost-calculation model and the overall pricing structure for the product will eliminate related concerns.

The licensor should define which public sector organizations could obtain the product at the preferred price. For pharmaceutical products, it should be clearly defined whether these public sector organizations can be only ministries of health, government purchase organizations, public sector hospitals, and similar institutions or if nongovernmental agencies with charitable functions, social marketing organizations in a country, international organizations with a humanitarian mission, and other institutions are also potential beneficiaries. The license should define how these agencies and organizations would be informed about the availability of a preferred public sector price for the product.

3.4 *Regulatory work and time-to-market*

Pharmaceuticals are subject to drug regulatory approval by health authorities, and the time required for the regulatory approval process increases the time it takes for a product to reach a market. It is good practice to stipulate in the license agreement when the licensee must bring the product forward to registration. It is also best to specify within what time period after signing the license agreement the licensee has to forward a complete registration filing to the relevant authorities. For a multicountry territory, specifying the sequence of registration filings in the various countries and the maximum time allowed between individual filings is vital.

It is also advantageous to specify how much time may pass between registration approval and the product launch in the public sector. This prevents the unusual, but realistic, scenario in which a licensee sits on its rights and doesn't utilize them for the benefit of the public sector.

3.5 *Avoiding the marginalization of the poor in small countries*

For commercial companies, large markets dominate priorities and occupy the top spots of territorial ranking, while small countries regularly occupy the bottom. This is because market attractiveness rules priorities in a commercial environment. The needs of the poor and of public sector agencies in small countries are not normally attractive markets for companies that are expecting to generate sizeable commercial returns from their manufacturing and marketing efforts. A licensor must ensure that product access is not limited just to larger markets and that small countries will be covered in order to avoid further marginalizing the poor.

When it comes to the territorial grant of a license agreement aimed at maximizing public sector benefits, the licensor must thoroughly consider this particular issue. The prospect of substantial profits from product sales in the private markets of any territory is an important issue for deciding to award the licensee commercial advantages under the license agreement. However, the territorial grant must cover not only large countries and their sizeable private

markets—as main incentive that the public sector would be reached as well—but also small countries and their public sector markets that the private sector partner would not normally cover. An effective territorial grant must contain a mix of large and small markets to balance the commercial potentials for the licensee against the humanitarian needs of the public sector. Only the licensor can guard these public sector interests.

It is good practice, therefore, not to grant sales rights in large countries to a single licensee without including an obligation to serve the public sector and markets in the smallest countries. If a single licensee cannot cover all of a region's markets, the entire region should be appropriately segmented to ensure that two or more licensees each get a profitable share and that the public sector in the smallest countries will be served. As outlined above, this goal needs to be adequately supported by specific milestones.

The up-front definition of territorial milestones is often skipped, or neglected, to the public sector's disadvantage. One very common reason for this is that the primary needs of the public sector are spread over a wide territorial area and/or over a variety of minority groups in dire need of services. Satisfactory coverage requires detailing a multitude of distinctive priorities and characteristic milestone definitions, a burden squarely placed on the initial license partners—especially the licensor.

One strategy for expanding territories is for the licensor to generate sales to public sector agencies in countries that are not covered by the initial territory grant but that need the product very much. This approach has the following advantage: the licensee can focus on the obligations and related milestones under the license agreement without facing multiple targets, while the licensor serves public sector agencies outside the territory and potentially establishes other useful partnerships. If desired, this additional market may be assumed by the licensee.

Setting a quantitative goal for public sector sales needs special consideration. The licensor could use absolute or relative target figures. The market share percentage reached after a certain time from product launch is one good target figure. Other possibilities would be to 1) define the sales growth reached in the first years on the market or 2) to use the sales volume after one, three, or five years on the market to characterize the expected—and initially agreed upon—success rate. The licensor could specify, for example, that the product should be among the top-three products within the specific market segment in its third year of introduction.

In the private sector, competitiveness is an important factor for measuring the success of any product. Licensees need to achieve the highest levels of competitiveness in private sector markets in order to be able to reach their commercial objectives. This in turn would support a very competitive manufacturing cost structure, which ultimately would provide the public sector with the lowest possible cost. Measuring private market targets is therefore, also an adequate way to express public sector goals.

Another way to set milestones for performance in the public sector is to set sales volumes in the private and public sectors in relation to each other. A powerful milestone definition, for example, specifies that public sector sales reach 40% (or any other agreed upon ratio) of the sales volume for the private market within three years after product launch.

With respect to the availability of the product in the public sectors, it is essential to specify expected launch dates for the product. For example, the license agreement could stipulate that the product be made available in the public sector not later than two years after the signing of the agreement. Should a product require initial sales in the private market for any reason, an adequate requirement for public sector introduction could be "*not later than X years after private-sector launch.*" For multicountry territories, specific requirements for each country would need to be established and defined.

Remedies for unmet milestones need to be part of the license agreement. One effective remedy is to significantly increase royalties on private market sales when a milestone has not been reached.

4. CONCLUSIONS: TOUGH MILESTONES FOR A TOUGH INDUSTRY

Finally, some thoughts about milestones for the cautious few who feel uncomfortable with the idea of setting tough milestones in a tough industry. In a process-oriented sense, milestones represent and define the outcome of standard operating procedures (SOPs) for organizations that have voluntarily subjected themselves to certification procedures, such as ISO. Why should the public sector not also define such SOPs and specific outcomes for the important targets of a license agreement?

However, one of the underlying assumptions for everything outlined above is that milestones are not cast in stone. Milestones should be and need to remain adjustable throughout the lifetime of a license agreement to respond to changes in the project, changes in the market environment, and other factors that cannot be anticipated. When it comes to the detailed specifications of individual milestones, it does not really matter if one is choosing an absolute or a relative goal, or which definitions are finally selected. What matters is getting a private sector company to commit to accepting public sector targets. To accomplish this, it is important to have a working set of adequate milestones in place, to define review periods for performance assessment by the contract partner, and to be ready to be open to, and to accept, milestone revisions when new, solid evidence requires a change of rules to keep the product and public sector goals alive.

Such result-oriented milestones require:

- intensive preparation
- detailed knowledge of processes related to product development and marketing
- detailed knowledge of markets
- realistic anticipation and forecasting of product potential
- persistence in quantitative forecasting and in establishing a master plan for the entire product roll-out
- a mission-driven mindset to establish the optimum public sector goals and to prevent the public sector from losing out to commercial thinking

Finally, it is crucial to recognize that public–private partnerships are not a magic solution per se for tasks that have not been well specified! In this sense, public–private partnerships are a poor substitute for specific, well-defined targets. In fact, successful public–private partnerships are built upon specific, well-defined targets. ■

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1 See www.ippph.org for a complete list.

2 www.ConceptFoundation.org.

3 PIACT, the Program for the Introduction and Adaptation of Contraceptive Technology, is a predecessor of PATH.

4 For a broader discussion on field-of-use licensing, see the chapter 10.3, also in this *Handbook*, by SL Shotwell. Also, the chapter by M Olson, also in this *Handbook*.

5 IMS is an international company that publishes reports on pharmaceutical sales by conducting pharmacy audits and other means.