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Intellectual Property and Licensing and their Impact on Global Public Goods for Health: Options for Public Sector and Academic Leadership

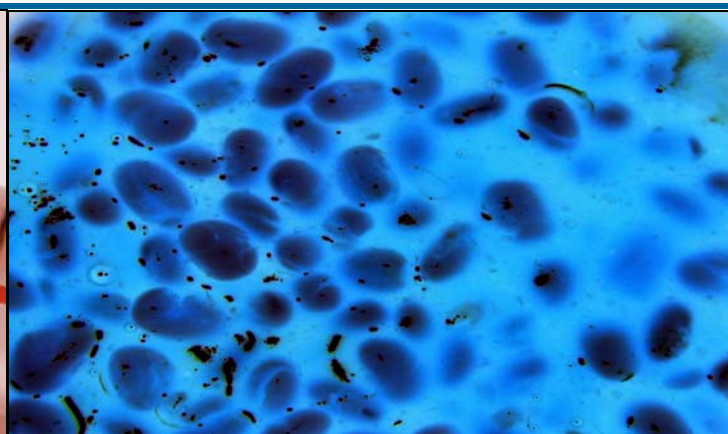
Gerald T Keusch

Building a "Cottage Industry" for Health (and Wealth): The New Framework for IP Management in India

R Saha R, K Satyanarayana and Charles A Gardner

The Role of Milestones in Licensing Deals to Assure Access to Health Products in Developing Countries

Joachim Oehler



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The Role of Milestones in Licensing Deals to Assure Access to Health Products in Developing Countries ¹

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Executive Summary

IP management to optimize public sector benefits needs to balance the commercial interests of private sector manufacturers with the needs of the public sector to obtain access to products at lowest possible costs. Most of the intellectual property (IP) oriented towards generating public sector benefits in the healthcare sector and biotechnology results from R&D in public-sector research centers and international organizations. Through adequate management of the resulting IP the public sector can benefit from its R&D investments through availability of the most modern products at conditions that are beneficial for the developing world, thus eliminating the otherwise significant access barriers.

An important tool of adequate IP management between public sector and private sector partners is the detailed definition of contractual milestones when it comes to licensing out IP from the public sector to private sector companies with the goal of producing products based on or incorporating the IP. This article describes in detail the considerations that lead to successful milestone definitions and discusses

¹ Oehler J. 2004. The Role of Milestones in Licensing Deals to Assure Access to Health Products in Developing Countries. *IP Strategy Today* No. 10-2004. Pp. 59-70.
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important factors related to pricing to the public sector; territory and exclusivity; regulatory work and data; time to market; royalties; and terms and termination of licensing agreements.

One of the underlying assumptions for everything that is outlined above is that milestones are not cast in stone. Milestones should and need to remain adjustable throughout the lifetime of a license agreement according to project development, changes in the market environment, and other factors that can't be anticipated completely. When it comes to the detailed specifications of individual milestones, it does not really matter if you are choosing an absolute or a relative goal, and which definitions to finally select. What matters is to get the commitment of a private sector company to realize public sector targets. It is important to have a working set of adequate milestones in place, to define review periods for performance assessment by your 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 very intensive preparations, detailed knowledge of processes related to the development and marketing of the product, detailed knowledge of markets, realistic anticipation and forecasting of product potential, the persistence for quantitative forecasting and for establishing a master plan for the entire product roll-out, and a mission-driven mindset to establish the optimum public sector goals and to prevent the public sector from losing out to commercial thinking.

Successful public-private partnerships are being built on value propositions from the public sector to the private sector partners that take advantage of the inherent capabilities of public sector organizations. It is the task of the public sector IP manager to identify the relevant capabilities that are important to a particular public-private partnership, and turn these capabilities into specific value propositions that help the private sector partner to realize its commercial goals, but without sacrificing any potential benefit to the public sector. In this context, it is especially important to overcome the common phenomenon of further "marginalization of the poor" in the small and smallest countries of the developing world. In a commercial environment it is market attractiveness that rules priorities. In a public-sector context, the poor in the smallest countries have the highest needs to get access to affordable products. Adequate and successful IP management of public-sector generated IP needs to bridge these two opposites. The experiences of the Concept Foundation, which are the platform for this article, show that this is possible.

1. Introduction: The Importance of Contracts

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. In terms of assumptions and remedies, contractual agreements differ considerably in quality and substance for cases when unforeseen and adverse effects prevent the contractual partners from reaching their goals. Too many contractual relations go sour because when everything seems predictable partners rush into agreements without carefully thinking about contingencies.

Without an early elaboration of clear provisions for contingency planning and crisis management, this "honeymoon" trap is why many contractual agreements contain unclear, foggy language and omit definitive, detailed, and enforceable conditions concerning not only the contractual rights but also the obligations of each partner and the specific countermeasures to be 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 when the agreement is being established. This can be a sure recipe for disaster when the unforeseen strikes, especially if the mechanisms to settle disputes over differing opinions about contractual performance are not clearly specified.

A typical contract specifies the subject matter, the rights and obligations of each party under the agreement, and the duration and terms. Licensing agreements between two organizations identify, among many issues, the nature and scope of the intellectual property or product that is licensed, spec-

ify the territorial grant to the licensee where the licensed product would be made available, and the terms under which the Licensor receives financial compensation from its licensee(s).

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 this IP and to distribute this product to consumers and users. The interests of both parties in this arrangement are straightforward and advantageous for each partner—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 for the times planned or forecasted, and the contractual partners are left with a subset of the original targets.

Such contracts between private and public sector entities must also consider that the commercial interests of private sector companies are on the whole oriented towards 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 that regulate target achievement under the license and set incentives for keeping to timelines and performance goals. This allows both the Licensor and licensee(s) to focus resources on their efforts to perform as initially agreed.

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

Most important milestones cover:

- Pricing to the public sector
- Territory and exclusivity
- Regulatory work and time to market
- Royalties
- Terms and termination of the license agreement

2. The Great Divide in Business Models: Public Sector–Industry

The discussion between the public sector and industry is a cross-cultural event, no matter how well public sector players think they understand industry. In such a cross-cultural environment, there is nothing more dangerous and productive of misunderstanding than to "assume the obvious", since what is obvious for one person with a public sector background will not necessarily be the same for the other 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, detailing when and how this will be achieved and specifying related penalties. If the agreement specifies only best efforts and unspecified performance, disaster threatens!

Value Propositions Stimulate Collaboration

To manage intellectual property for maximized public sector benefits requires balancing the expectations of the public sector to obtain products at the lowest possible prices, excellent quality, and in sufficient quantities, with the expectations of private sector companies to generate a satisfactory rate of return on their manufacturing and marketing efforts.

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 and/or clinical research using an existing network of public-sector institutions in parallel speeds the generation of results needed for drug regulatory approval without 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 and actual values need to be based on the set of capabilities, which actually are the platform for all actions that results in value creation, that the public-sector organization could offer and on what needs of the private-sector partner could be met by a public-sector partner. Such genuine values include the examples above: "save time to market", "save resources", and "save investments." As these demonstrate, it is important to 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 contributions. Indeed, an authentic value proposition is more often composed of several contributions from various capabilities than a single value factor.

It is very helpful to understand all the specific values at a very early stage of approaching potential licensing partners that drive an industry and that are particularly important for the potential licensee. A detailed analysis of these values and alignment with existing public-sector capabilities help to identify the value propositions that public-sector organizations could offer their private sector partners.

3. The Most Important Milestones

3.1 Principles

The management of intellectual property for maximized public sector benefits has three key aspects:

- Definition of the geographic coverage for marketing the product (i.e., territory)
- The claim for product exclusivity by the private sector licensee(s)
- The definition of the preferred public sector price or other public sector benefit

These headlines seem very straightforward. It is easy to imagine that the partners in a license arrangement agree on a set price for the product for public sector distribution, agree on the names of the countries where 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 a maximization of public sector benefits.

Some key questions need to be answered to safeguard the maximization of public sector benefits:

- How well will we reach smaller countries with our product?
- How well will we reach the rural population in developing countries that, by all experience, normally remains underserved?

- Who will be the beneficiaries that can obtain the product at a special public sector price?
- How can we assure that we obtain the product at prices that public sector agencies can afford?

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 commercially are not interesting enough to generate sizeable returns on investments and would therefore normally not be served). Finally, there needs to be a clear framework to compute the manufacturing cost.

Due to commercial pressures, there is an inherent danger of putting the private sector and its commercial interests before those of the public sector. This danger mainly results from 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 the targets to achieve and on the issues to exclude. A tight focus will secure simplicity of the provisions and regulations without overburdening an agreement.

When it comes to public sector benefits, making a product available or how quickly it reaches markets does not constitute progress. It is how many people the product will reach, how easily it will be available, and who can afford the product at what pricing level that defines success. The goal is to reduce morbidity and mortality to the greatest possible extent. For the public sector, This is the ultimate benefit of product development. The necessary achievements for obtaining this outcome need to be clearly specified as milestones in the agreement. Accordingly, we will take a closer look at territory, exclusivity, and pricing.

3.2 Territory and Related Aspects

A typical license agreement will specify the grant of the license in one of its early paragraphs. 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.

Under this wording, the license grant is established as a right of the licensee to the product. However, it doesn't 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 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 multi-country 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 at the time when the license agreement was established.

Between the signing of a license agreement and the commercial rollout of the product, a considerable period of time may be needed for product development, manufacturing scale up, and drug regulatory approval for a pharmaceutical. 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 very attractive may lose their appeal over time compared to other opportunities since recognized by the company.

Changes in the business environment and business focus may affect the licensee's commitment to serve the public sector as originally envisioned for the entire territory. To avoid negative consequences for

public sector availability and public sector access to the product in the territory, it is only prudent to establish the license grant as an obligation to sell the product into the public sector of the territory—not just as a right of the licensee. This can be accomplished in various ways:

- One possibility is to separate 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.
- Another possibility is to assign milestones to the execution of the sales rights for the product under which the licensee would gain access to other countries. Only after showing defined success according to the milestones the licensee would be granted additional sales rights for other countries.
- Public and private sector rights to selling the product could be dealt with in separate regulations that capture the priority for the public sector organization of having the product introduced into the public sector to 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, as example, the rights of a Brazilian manufacturer to produce and sell the product in Brazil, its home market, and the rights to sell it in other Latin American countries when 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 IMS².
- *Market position*: licensee will gain the rights to sell into other countries after positioning the product among the top 3 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 5 million units is realised 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 10 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, or eventually the Licensor as well. Each country on the list will then be characterized by individual milestones that need to be reached by the company before it could sell in an additional country. These country priorities and milestone definitions should be set initially 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 (e.g. saying, that the next country priority will be set shortly before reaching the last defined milestone in the actual country of activity, or a similarly flexible model that postpones decision-making). This carries the risk that it might get more and more difficult to reach the necessary consensus between licensor and licensee about country priorities and milestone definitions, 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 into the public sector, due to various, possibly hidden reasons, which would run contrary to the goals of the public sector organization at that time. In a flexible licensing model, if milestones had not been mutually defined before such a situation emerges, the private-sector company would not violate the license agreement if the necessary consensus about mile-

² IMS is an international firm that publishes reports on pharmaceutical sales by conducting pharmacy audits and other means.

stone definitions cannot be reached between the contract partners, and could walk away from its responsibilities to serve a particular country.

On the other hand, priorities and milestone definitions may change over time in a fast moving business environment and they might not be considered valid after several years in the lifetime of a license agreement. This is a common perception when it comes to the definition of 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 the inherent dangers of leaving important parts of an agreement initially undefined pending a mutual understanding at a later time, 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, for example, 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 and convincing reasons for the licensor, the original definitions of priorities and milestones will prevail. The originally anticipated public sector goals and benefits remain in force without alteration and are still to be realized by the licensee.

Initially defining contractual priorities and detailed milestones is, of course, a painful process that requires very intensive preparations so that the essential aspects of public sector needs are not overlooked. This phase of desk research and information collection is among the most important phases for adequately preparing license agreements serving public sector interests. For initial negotiations between parties, it is most appropriate to roll out the terms of a licensing arrangement in all related details, even though it may be difficult and resource-intensive to formulate all of them. Calls from the contract partner or one's own tendencies to postpone detailing specifications or omit the necessary depth of description for the benefit of simplifying and quickly reaching an agreement are not beneficial for establishing the necessary framework of an efficient and ultimately effective public sector oriented licensing arrangement. If it is not possible to reach an agreement on staggered priorities with detailed milestones in the beginning of the contract relationship, how can these differences satisfactorily be ironed out later?

3.3 *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 end up at the bottom of the priority list. In a commercial environment, market attractiveness rules priorities. The needs of the poor and of public sector agencies in small countries do normally not represent attractive markets for companies that are expecting to generate sizeable commercial returns out of their manufacturing and marketing efforts. It is necessary for a Licensor to ensure that product access is not limited to larger markets only and that small countries will also be covered to avoid further marginalizing the poor.

When it comes to the territorial grant of a license agreement aimed at maximizing public sector benefits, this particular issue needs to be considered thoroughly by the licensor. The prospect of substantial profits from product sales into the private markets of any territory is an important issue for awarding the licensee commercial advantages under the license agreement. However, the territorial grant must not only cover large countries and their sizeable private markets -as main incentive that the public sector would be reached as well -, but needs to also include small countries and their public sector markets that normally would remain uncovered by the private sector partner. It is vital for an effective territorial grant to contain a mix of large and small markets to balance the commercial potential for the licensee against the humanitarian need of the public sector to provide access for the poor to affordable and effective products also in those countries that are commercially not attractive. This particular need is left to the protection of the licensor as the guardian of public sector interests.

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

The upfront 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 for services. Satisfactory coverage requires a multitude of distinctive priorities and characteristic milestone definitions, which places a burden of initial definition on the license partners, especially the licensor as guardian of the public sector interests.

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 very much need the product. This approach has the following advantage: the licensee can focus on the obligations and related milestones under the license agreement without dilution through multiple targets, while the licensor seeks to serve public sector agencies outside the territory. If desired, this additional market may be assumed by the licensee.

An issue for special consideration is the setting of a quantitative goal for public sector sales. The licensor could use absolute or relative target figures for the size of the public sector sales. A good target figure is the market share percentage reached after a certain time from product launch. Another possibility is to define the sales growth reached in the first years on the market. You could use the sales volume after 1, 3, or 5 years on the market to characterize the expected—and initially agreed upon—success of product introduction. You 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.

Competitiveness in the private sector is an important success factor for any product. Licensees need to gain highest levels of competitiveness in private sector markets for being able to reach their commercial objectives. This will –in return- support a very competitive manufacturing cost structure, which ultimately provides the public sector with lowest possible cost. It is therefore adequate to also express public sector goals by measuring private market targets.

Another way to set milestones for performance in the public sector would be to set sales volumes in the private and public sector in relation to each other. A powerful milestone definition is to specify, for example, 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 public sector availability, it is mandatory 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 signing the agreement. In case a product requires 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 multi-country territories, individual 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 sales in the private market when a milestone has not been reached.

3.4 Exclusivity

Exclusivity is one of the first things that companies ask for. It is important to link such requests with specific milestones. Such milestones can be:

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

Equally important to setting specific milestones is to specify penalties and fines for the licensee if these milestones haven't been reached. Examples are:

- 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 non-exclusive license in general or for a specific territory.
- Loss of exclusivity and territory to a competitor.
- Payment of a fine in a predefined amount for the failure to introduce a product into a country under exclusivity for the licensee.

It is good practice to evaluate the request for exclusivity against the level of public sector benefits that a potential licensee could deliver. Again, it is unreasonable to expect that a private sector company will concentrate major resources on serving the public sector as long as there are no specific obligations in a license agreement or adequate milestones have not been defined. 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, and eventually to regulate in the license agreement, what kind of resources-qualitatively and quantitatively-the private sector company will make available and mobilize to work in the public sector segment of the exclusive territory.

3.5 Pricing for the Public Sector

A key issue for the public sector in developing countries is the affordability of products that are brought into the market. Prices must ensure the widest possible availability. Price calculations are done 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. Adequate product positioning into affluent markets to a large extent determines achievable margins and operating profitability. The public sector, in contrast, 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 burden the product 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. The aim of this cost calculation model is to understand all directly and indirectly attributed product costs that contribute to final cost. By applying this tool and marking up the ex-factory product price with a mutually accepted profit margin for sales into the public sector, a reasonable platform for the determination of the lowest possible public sector price can be achieved. For indirect costs it is necessary to determine if the cost

burden on the product is fairly allocated. 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 regular submission of manufacturing cost reports and product cost calculation details on an annual basis. Furthermore, it is important for the Licensor to reserve the rights to have these cost reports audited by independent auditors.

Should a manufacturer be unable to match expected price levels for the public sector when the company begins manufacturing and is still at the beginning of the learning curve, it is necessary to set a definite time line for when expected price levels must be reached. Adequate penalties have to be in place for this case. It is important to recognize that a license agreement can not be a tool to force a manufacturer to produce a product below cost, however, the detailed agreement on the manufacturing cost calculation model and the overall pricing structure for the product will eliminate related concerns.

The licensor should define which institutions are the public sector organizations that can obtain the product at the preferred price. For pharmaceutical products, it should be clearly defined if these public sector organizations are only ministries of health, government purchase organizations, public sector hospitals, and similar institutions, or if non-government 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 will be informed about the availability of a preferred public sector price for the product.

3.6 *Regulatory Work and Time to Market*

Pharmaceuticals are subject to drug regulatory approval by health authorities. The time needed for the regulatory approval process prolongs the period for a product to reach a market. It is a good practice to stipulate in the license agreement when the licensee must bring the product forward to registration, and it is best is 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 multi-country territory it is vital to specify the sequence of registration filings in the various countries and the maximum time allowed between individual filings.

It is also advantageous to specify how much time may pass after a registration approval has been obtained until the product is actually launched into the public sector. This prevents the unusual, but realistic scenario of a licensee "sitting" on its rights and not utilizing them for the benefit of the public sector.

4. Conclusions

4.1 *Setting 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.

One of the underlying assumptions for everything that is outlined above is that milestones are not cast in stone. Milestones should and need to remain adjustable throughout the lifetime of a license agreement according to project development, changes in the market environment, and other factors that can't be anticipated completely. When it comes to the detailed specifications of individual milestones, it does not really matter if you are choosing an absolute or a relative goal, and which definitions to finally select. What matters is to get the commitment of a private sector company to realize public sector targets. It is important to have a working set of adequate milestones in place, to define review periods for performance assessment by your contract partner, and to be ready to be open to and to accept mile-

stone revisions when new, solid evidence requires a change of rules to keep the product and public sector goals alive.

Such result oriented milestones require:

- Very intensive preparations
- Detailed knowledge of processes related to the development and marketing of the product
- Detailed knowledge of markets
- Realistic anticipation and forecasting of product potential
- The persistence for quantitative forecasting and for 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

In a process oriented sense, milestones represent and define the Standard Operating Procedures (SOPs) of organizations that have voluntarily subjected themselves to certification procedures, such as ISO. Why shouldn't the public sector also define such SOPs for important targets of a license agreement? It is crucial to recognize that public-private partnerships are NOT the magic solution for tasks that have not been well enough specified! In this sense, public-private partnerships (PPPs) should not represent a poor substitute in absence of specific targets for public sector benefits.

4.2 Achievements of the Public-Private Partnership Model:

The Work of the Concept Foundation to Close the Medicines Access Gap Specific to Developing Countries

The role of Public-Private-Partnerships (PPPs) 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, and around 86 PPPs (see www.ippph.org for a complete list) have been established worldwide in the meantime. However, PPPs' accomplishments as indicators for the PPP model to succeed in its goal are rarely publicized, partly because most of these entities are relatively young. Half of these partnerships have been established in the past few years since 1999 (www.ippph.org). This is a very short period of time in a pharmaceutical R&D or health care environment where normally times to market are ranging from not less than 10 to around 12-15 years on average.

The Concept Foundation (www.ConceptFoundation.org) was established in 1989 through an initiative funded by WHO's Special Programme of Research, Development and Research Training in Human Reproduction (WHO/HRP), with the support from PATH/PIACT and additional funding by the World Bank and the Rockefeller Foundation. The mission is to "Provide access to top quality reproductive-health products for developing countries at lowest possible prices and 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". Concept Foundation has accumulated extensive experience with project management of health technologies development and with technology transfer to roll-out new technologies in the developing world.

The R&D process for product development of new drugs, vaccines and also diagnostics in the diseases of poverty is a crucial step towards ultimately eradicating the disease burden in the poorest regions of the world. Many PPPs concentrate their efforts on the product development approach, and the largest product development PPPs have successfully raised (in combined figures) more than half a billion US dollars in recent years to acquire the R&D funds needed to fuel their development work. However, product delivery is an equally important, if not even a more decisive, factor of access to medicines, and

most product development PPPs are not active in delivery of their products into local health infrastructure. There are no significant experiences reported with the downstream issues involved in bringing products into markets there where they are most needed.

Future concerns for product development PPPs to solve will be how to handle and finance downstream issues for introduction and launching new products in diseases of poverty to close the medicines access gap for public health services when public health factors, such as:

- adequate health infrastructures,
- disease surveillance,
- compliance monitoring,
- education and training of health workers and medical staff,
- improving health care facilities,

and similar issues come into play, besides further important soft factors such as

- physical distribution networks,
- satisfactory supply volumes,
- adequate volume forecasting,
- minimizing product waste at the point of treatment,

and others, to name but a few of the most important issues to deal with.

As we know well from the experiences in pharmaceutical industry, a significant and decisive part of the cost structure for new medicines is related to bringing a new product to markets through effective and successful programs of marketing and distribution. While nobody would expect the need to create market demand (= invest marketing dollars) for new products to fight diseases of poverty, the inability of the poorest regions high in demand for effective medicines to pay for new products and the supply, distribution, as well as surveillance problems to reach all who need treatment, will demand huge additional investments and other type of public-private partnerships at work on the downstream issues before all goals are being reached.

These efforts must include reaching lowest possible manufacturing costs for the ability to forward preferential pricing to public health services and closing the medicines access gap in the developing world, establishing sustainable manufacturing with a continuous system for quality monitoring and creating a business model, financially attractive to private pharmaceutical companies, to overcome the disincentives from poor expected return by operating in public sector markets. The achievements of the PPP business model exercised by Concept Foundation to realize these goals, dealing with the downstream issues around product delivery, demonstrate broad success in the principal goal to close the medicines access gap for developing countries.

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