

**Warren Kaplan, PhD, JD, MPH**  
**Center for International Health & Development**  
**Boston University School of Public Health**  
**Boston, MA**

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## Executive Summary

For-profit firms may acquire knowledge as well as the legal right to exploit technology that is patented and is otherwise not capable of being exploited without a license. Similarly, firms may be the creators of knowledge and proprietary technology that they would like third parties to exploit. In this context, license and other agreements negotiated by businesses can be viewed as a means of managing the significant risks involved in pharmaceutical research and development. Pharmaceutical research and development is complex, long and costly. Technology that a firm would like to acquire may be in a very early stage of development. Notwithstanding the large amount of monetary and intellectual resources that are involved in pharmaceutical R&D, it can be likened to drilling for oil, as much pharmaceutical R&D results in “dry holes” so that no marketable product is produced.

Notwithstanding, the fact that partnerships between the for-profit and non-profit sectors (e.g., public private partnerships- PPPs) exist at all is testament to two conditions: millions of people globally die or become disabled from diseases for which there are no or inadequate medicines and the free market has no incentive to develop such medicines. Although PPPs that have been formed in response to this market failure also must view contractual IP agreements as a way of ‘managing risk’, they have another agenda, i.e., to make sure that the new product emanating from the PPP will be as affordable as possible for citizens in developing countries.

The concept of “affordability” means that a licensee must provide the product at prices that patients can afford, or retain the right to limit the price of the products when sold. However, it is likely extremely difficult to get parties to a negotiated agreement to agree to conditions regarding prices, even if applied only to developing countries. This is particularly true for “early stage” technology that carries a risk of never being a product. Also, for-profit entities do not want to commit to any price structure too early. Further, although not discussed in this report, there are antitrust issues with regard to setting prices, not matter how laudable the intent. On the other hand, price is an easily measurable condition that could be easy to implement but so many structural and functional components of the healthcare system in developing countries are beyond control of a PPP, that specific stipulations about “price” are rarely seen. It is difficult to price “affordability”. For a non-profit PPP the challenge is to come up with drug that can be incorporated into the existing price structure. Moreover, if the intent of the PPP is NOT to make money, and the expectation is that “nobody makes money on this arrangement”, structuring such an arrangement can become complex if there is a for-profit partner.

Instead, contract language often implies the price i.e., a stipulation that the cost of final product could be the cost of production (assuming one or both parties knows this), plus some reasonable mark up that is negotiated in advance. For drugs only supplied to low-income markets, products could be priced at average cost; in contrast, for drugs sold in both high- and low-income markets, products for the poorer countries could be priced at marginal cost, since profits from higher income markets could cover fixed costs. Prices could include income-adjusted margins for countries with greater ability to pay, such as lower- and upper-middle income countries.

The more common proxy for “price” is “access”. Some contractual language includes an access metric that would trigger certain actions on the part of the IP licensor if certain “access” conditions are not met (e.g., prices are being charged at greater than some percent of marginal cost; the poorest members of the population are not receiving the product because of price).

- A PPP can help in determine “access” by posing requirements for further development by others depending on various circumstances, such that for instance, a license is granted in “Developing Countries” [either a pre-set list or defined by national economic indicators...] under the IP for treating [condition X]...”
- A PPP can help determine “access” by attempting to segment markets within countries (into public and private).

- A PPP can request various “white knight” stipulations, which require the licensee to provide for the establishment of a benefit flowing from the technology supplier or user to the local community.
- A PPP can create a “non-suit” agreement which, in effect, bars the holder of intellectual property, from enforcing the IP within a certain set of countries and under a certain set of conditions. In essence, a typical IP license agreement is an implied “non-suit” agreement as the licensee would infringe the IP owner’s rights but for the license agreement. A “non-suit” makes this “permission to exploit” explicit. Such contract language is not common in PPP agreements but deserves further study.

The fact remains that current contractual language cannot ensure affordability or equitable access to a product. Even the lowest prices charged may not be affordable. A well-thought out contract is necessary, but insufficient, to make sure that all stakeholders respect human rights norms and ethical standards.

## **Introduction**

It seems beyond debate now that there is an immense unmet need for new treatment options for diseases that primarily affect people living in developing countries. This need has arisen because, although the market potential is enormous, governments as well as end users (i.e., patients who end up paying out of pocket for most medicines) have little money to pay the ‘rent’ demanded by intellectual property protection as presently required by pharmaceutical R&D to support the needed research. Patents can be justified, however, if they would create incentives to develop future technologies but where there is no market, patents alone cannot spur innovation. Any reasonable business model suggests that it is just not worth the effort for large international pharmaceutical companies to develop medicines for ‘neglected’ medical conditions and populations. Some new remedy, e.g. public funding for research and development for diseases prevalent in developing countries is necessary.

The present task is to review of the uses and public health implications of available license and other agreements negotiated between public private partnerships (PPP) and owners of intellectual property (IP) and/or non-patented technology. In some cases, the PPP may itself be the owner of IP and/or non-patented technology. The scope of this exercise is to provide a practical review of these legal documents in order to see if the language in these agreements promotes the objectives of the PPP in providing products that are as “affordable” as possible for developing countries.

This document is divided into four sections. Section 1 is an introduction to the issue of IP management in public private partnerships and the concept of “risk” and uncertainty. This section reviews some of general IP principles that product PPPs need to bear in mind when trying to manage the risk of product development. Section 2 is a brief summary of the various contract instruments that are available to PPPs. Section 3 is a practical review of selected documents with specific information on “affordability” contract language. Section 4 is a summary with recommendations for the future.

This document is not a review of the very complex policy issues related to IP management and non profits and developing countries nor is it an IP licensing or contracting law primer, although we necessarily have to discuss specific contract language in the context of this document. Legal jargon will be kept to a minimum.

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## 1. Risk and uncertainty in pharmaceutical product development:

Much of twentieth century legal drafting is derived from the experience of lawyers working in the context of the nineteenth century- a period where the Victorian belief that “solutions will be found” for even the most difficult problems was based in large part on the seeming ease with which science was capable of explaining the physical universe.<sup>1</sup> The elaborate and repetitious style of much legal drafting, beginning about 100 years ago and continuing to the present day, is testament to the search for semantic certainty. To those legal drafters who lived long enough to see even the beginnings of the twentieth century, it must have come as a shock that in the discovery of uncertainty- from principles of quantum physics to economic theory- all definitional systems have undefined elements. Underlying such definitions is inherent risk.

One of the characteristics of drug development projects is its inherent riskiness. Notwithstanding Einstein’s assertion that “God does not play dice...”, modern pharmaceutical drug development is a further testament to the continuing trend in science and technology of disclaiming certainty. Pharmaceutical research and development is complex, long and costly. Basically, drug development, is more complex than new product development in other industries because there are many projects being conducted in parallel, the development is highly regulated, it takes a long time to develop a product, and a large amount of monetary and intellectual resources are involved. Animal testing continues throughout the development period. The drug must be developed into a form that is effective to manufacture and production plants must be designed and even built. Marketing strategies and campaigns must be planned during the early stages of drug development. Specialists of regulatory affairs must be continuously involved in the development effort. The time to bring a pharmaceutical product into markets has the potential to become longer mainly due to developing drugs for chronic diseases which requires more clinical trials, more patients, and thus more time. Drug development has increased in complexity because the tools used and target diseases have become more complex. This complexity and increased time used in development has induced a rise in costs. For instance, for HIV, one cannot simply predict utility in humans from any animal model. This means that one cannot predict safety in humans until one goes a real efficacy study and that is a big, expensive risk.

The risk of failure has also an effect on costs: a few very successful products must cover the R&D costs of failed development projects. When expenses of project failures have been included, the cost of developing a new drug was calculated to be \$802 million US in 2000 while in 1987 the figure was \$231 million US.<sup>2</sup> The following summarizes some of the risks in pharmaceutical R&D.

### Risk level

- Of 5000 screened compounds one product is launched.
- Of all launched products only 30% pay back the R&D investment of the project.
- Big companies may, or may not, have enough products in their pipeline to recover R&D costs.
- Smaller companies cannot afford to develop many drugs simultaneously, thus risks are higher.

### Complexity

- Many parallel projects.
- Highly regulated development.
- Length of development.
- Amount of resources needed.
- More complex tools and target diseases.

### Length

- It takes at least 8 years and as much as 10 to 15 years to develop a new drug.

### Cost

- The cost of developing a new drug by the pharmaceutical industry has risen from \$54 million (US) in 1976 and \$231 million in 1987 to \$802 million in 2000 to probably \$1 billion (US) in 2004<sup>2</sup>
- Increased R&D spending of 10% a year in top twenty companies.
- Output less than one completely new drug per year.
- Potentially ineffective use of resources because of the development of 'me-too' drugs.
- Staff costs account for a significant portion of R&D costs.

### ***1.1 Public Private Partnerships (PPPs)***

This enormous and risky R&D expenditure has largely been at the expense of diseases of poor countries. According to the Global Forum for Health Research, "Every year more than US \$70 billion is spent on health research and development by the public and private sectors. An estimated 10% of this is used for research into 90% of the world's health problems. This is what is called 'the 10/90 gap'"<sup>3,4</sup> During the past ten years, the global health community has identified gaps in research and development of medicines to prevent or cure diseases that are primarily associated with extreme poverty and its attendant lack of access to clean water, adequate nutrition, and basic sanitation.<sup>5</sup> While diseases such as malaria, tuberculosis and others that are even less well known are rampant in developing countries; they are virtually unheard of in developed countries<sup>6,7,8,9</sup> Not only is there little or no economic incentive to develop pharmaceutical products<sup>10,11</sup> for these diseases, other issues abound: i.e., distribution challenges in countries with poor infrastructures and lack of awareness about these diseases in more developed countries, liability considerations, inadequate science base, and underestimation of the disease burden<sup>12</sup>. As a consequence, a minimal amount of research has been conducted.

Impelled by the knowledge that millions of people globally die or become disabled from diseases for which there are no or inadequate medicines and seeing that the free market has no incentive to develop such medicines, various initiatives between the public and private sectors have been created to fill this void. These have been called 'public-private partnerships' (PPPs). The term PPP misrepresents the true diversity of these initiatives. They bring together skills, knowledge, and resources from a variety of sectors including academia, non-governmental organizations, philanthropists, not-for-profit organizations, government and intergovernmental agencies, as well as members of the for-profit private sector such as pharmaceutical and biotech companies. From 1986 when the first PPP for health was created until the end of 2003, ninety-one such partnerships have been instituted, 78 of which are still in existence. Each partnership has its own separate legal status, broad range of goals, and combinations of partners from the public and private sectors, management structures and strategies.<sup>13, 14</sup> . The spectrum and mix of public and private entities involved in any one partnership can range from an organization such as Drugs for Neglected Diseases Initiative which as of early 2004 had no representatives of the private sector on its Board of Directors<sup>15</sup> to the non-profit Pharmaceutical Security Institute whose members are companies that are research-based for-profit multinational pharmaceutical firms.<sup>16</sup> The International Trachoma Initiative is comprised of a for-profit entity, a private foundation, national governments, other private foundations, non-governmental organizations, and the World Health Organization.<sup>17</sup> Many partnerships reflect a mix of representatives from the public and private sectors on their Boards of Directors some of whom represent a particular institution while others sit in an individual capacity; however, it remains unclear which model is optimum for ensuring success.

#### **1.2.1 Product PPPs**

The nature, variety, and individuality of public-private partnerships make definition difficult.<sup>18,19,20</sup> A "species" of the "genus" PPP, are those entities specifically initiated to develop a pharmaceutical product. For a working definition, we define a "product development PPP" as an arrangement that innovatively combines different skills and resources from institutions in the public and private sectors to develop a pharmaceutical product. The vast majority of product PPPs was formed in the past seven

years and so we lack a comprehensive understanding of their advantages and disadvantages, and whether or not they can do what they set out to do and fill the pharmaceutical R&D “funding gap.”

### **1.3 Managing Risk in a product PPP**

The private sector pharmaceutical industry has managed risk by using intellectual property, particularly patents, to provide exclusivity for a marketed product and to extract monopoly “rent” from users of the patented product usually in the form of royalties on product sales. Obtaining IP protection for a commercial product can lead to improvement in market position in local and global markets; improvement of the “visibility” of the enterprise; increased opportunity for licensing and other business transactions; and possible use as income or for leverage/“bargaining chip” purposes. Patents might also be sought to exercise control over such activities as product development, manufacturing, marketing and distribution of products (including avoiding a situation where the PPP activities are “displaced” by the commercial activities of third parties). For further reading on the complex question of IP management in pharmaceutical R&D see reference [21].<sup>21</sup> For reading on IP management for similar issues in agricultural R&D see reference [22].<sup>22</sup>

Risk management through IP will in principle be different for the different partners in a product PPP. Some PPPs with primarily non-profit components will have a far different view of risk than those with for-profit components. Indeed, the private sector may not always be the holder of technology in a multiparty product PPP. If a product PPP has a for-profit partner, patent exclusivity is clearly a crucial factor to the success of any product but there is no return on the heavy investment for R&D until the patented invention becomes a commercial success. Further, initial patent filings usually have to be made during the early stages of a research program when the commercial success of the product is unknown.

Two overall risk management strategies have been well reviewed by Taubman.<sup>23</sup> “Technology development and access obligations” deal with research and creation of new technology per se, or the availability of necessary technology and associated data. This strategy creates obligations on the research/industry partner to undertake research and development, and to make available background IP, know-how and associated data (including technical know-how or skills and resources required for product development, clinical trials and regulatory approval know-how, as well as the data on safety and efficacy produced by clinical trials).<sup>23</sup> These provisions may require an obligation to license or transfer IP rights in the event the research/industry partner fails to, or has insufficient interest to, develop and disseminate covered technology in a particular market.

“Downstream technology dissemination obligations” stipulate conditions as to how the covered technology (typically a pharmaceutical or vaccine) is to be distributed or marketed by the research/industry partner. Unless the product is near to, or already on, the market, these price stipulations that set a certain price are rare. More commonly, such obligations set out price criteria for determining the price for distribution in a certain market so that the pharmaceutical will be ‘reasonably available’ or “cost plus” or otherwise comply with similar criteria. These obligations may also provide distinct requirements for how the pharmaceutical is to be distributed in distinct markets, such as an undertaking to cross-subsidize developing country or public sector distribution on the basis of preferential pricing, and other conditions defining how access to the covered pharmaceutical should be granted on the basis of market or non-market mechanisms.

If a product PPP is interested in ensuring “affordability” to product PPP outputs, IP considerations may be complex and uncertain. A product PPP has many IP options but they may work at cross-purposes. One option would be to put into the public domain all information, whether legally protectable or not. However, it may be that some outputs would be better protected as intellectual property, which can then be leveraged to further its aims.<sup>24,25</sup> For non-profit product PPPs, whose mission is to ensure that drugs are affordable and access is equitable for patients who need them, there is a desire to develop drugs as public goods when possible.<sup>25</sup>

Particularly for the non-profit member of a multiparty product PPP, or for a product PPP that is entirely non-profit (e.g., Global Alliance for TB) what may be more important than maintaining their own exclusive IP position is “freedom to operate” in a field that can be crowded with the patents of competitors or with technology that will hinder the ability of the PPP to produce the product. Such “freedom to operate” is not free and comes at a price (including opportunity and transaction costs), as this may involve negotiating licenses with holders of third party IP (See Section 2.4).

## 2. Turning Theory into Practice: Forms of Negotiated Agreement

A contract such as a license is a legally enforceable agreement that consists of an exchange of negotiated promises or actions between two or more people which creates an obligation to do, or not do, something. The agreement creates a legal relationship of rights and duties. If the agreement is broken, then the law should provide certain remedies. There are three factors necessary to create a “contract”: 1) an offer, 2) acceptance, and 3) “consideration” (a bargained-for exchange). One party makes an offer, the second party must accept the offer and there must be consideration exchanged. Consideration has to be something of value. Complex agreements can be generated where simple contracts merge into one another or be incorporated in successive iterations of a larger, ‘blanket’ agreement.

What follows is a brief summary of some of these contractual forms relevant to the present discussion:

### 2.1 *Material transfer agreements (MTA)*

An MTA establishes standards for the transfer of biological resources for research and possible commercialization in exchange for benefits to the party recognized as the supplier. This might be a government, a collecting organization (such as a botanic garden), or even a local community. Such benefits may be in the form of up-front benefits or future royalties. In exchange, MTAs usually grant the recipient of the material the right to apply for patents if any of the material has commercial potential.

**Confidentiality:** When confidential information is exchanged along with the material, the supplier of the material may request that such information not be further disclosed. If the information is necessary for interpretation of the research results obtained using the material, that same information may also be required for publication of those results. Having agreed to hold the information confidential could prohibit a PPP investigator from ever publishing the results of work using the supplier’s material although this is probably not an issue for product PPPs.

**Use of materials in sponsored research projects:** Many for-profit MTAs contain language that prohibits the use of the material in research that is subject to licensing or consulting obligations to any third party, including the sponsor of the research project.

**Definition of material:** An industry provider may propose a definition of material that includes not only the original material, but also modifications or derivatives made from the material that incorporate the investigator’s original ideas or concepts. If the provider also claimed ownership of the modified material, the provider could own the results of the PPP’s research. The PPP could be prevented from using research results in further research, transferring them to other organizations, meeting obligations to research sponsors, or ensuring that the results are made public.

**Loss of control of intellectual property:** If MTAs pre-empt ownership rights, PPPs may be restricted in their ability to interact with a future sponsor or may have conflicts with obligations to current sponsors. Intellectual property restrictions may prevent the PPP from conferring rights on a future developer.

**Conflicts with existing agreements:** Industrial MTAs may contain obligations that conflict with obligations in a pre-existing agreement. Also, the material may be used in conjunction with a separate material received under another MTA. These situations could result in granting two or more parties conflicting rights to the same invention.

## 2.2 *Know how agreements*

“Know how” can be defined as specific pieces of information which are themselves secret or which is not generally known or readily accessible to persons (formulations, blueprints, customer lists, manufacturing conditions, cell lines and so on). The legal status of “know-how” throughout the world has been problematic. Generally, if a pharmaceutical company wishes to transfer this information to a PPP or a PPP wishes to transfer know how to a contract manufacturer, one must impose upon the recipient a set of conditions to ensure that the information being imparted is kept secret. This can sometimes prove difficult in negotiation of an agreement where the prospective receiver asserts that it must be free to disclose information for example to its customers or to government agencies. If a substantial portion of the value of the contract, however, relates to the supposed secret information then one has really no alternative but to insist that appropriate safeguards are included. The exact legal status of “know-how” as a property right remains rather unclear. Article 39 of the TRIPS agreement requires countries to provide for protection for “undisclosed information” and in particular requires that natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

- is secret in the sense that it is not generally known among or readily accessible to persons “within the circles that normally deal with the kind of information in question”;
- has commercial value because it is secret; and
- has been subject to “reasonable steps under the circumstances”, by the person lawfully in control of the information, to keep it secret.<sup>26</sup>

## 2.3 *Sponsored Research Agreements*

Sponsored research agreements are the contractual mechanism through which outside entities provide financial support to research conducted by a product PPP. Of course, PPPs can also enter into such agreements if they wish contract research work to be done for them. Researchers work with the outside sponsor to define a scope of work and budget for the project, which are then attached to the contract as exhibits. Sponsored research agreements can lead to new inventions, or may be entered into as part of a licensing deal for an earlier invention to continue the involvement of the inventors in the further development and testing of the invention.

Dealing with IP rights in such contracts illustrate the issues that for-profit and non-profit entities face. For profit research sponsors often wish to receive rights to negotiate an **exclusive** license to inventions and/or discoveries made through the sponsored research project by the PPP researchers. These exclusive rights should certainly be subject to a worldwide, non-exclusive, royalty-free right to use these inventions and/or discoveries retained by the PPP for its non-commercial activities but product PPPs will also need a commercial license to whatever inventions and discoveries are made in the course of the sponsored research.

## 2.4 *Licensing agreements*

The legal definition of a license is permission granted to do something that would otherwise be illegal if not permitted. In the context of intellectual property, an IP license is a contract between two or more parties. The owner of the IP or entity that has a legal right to offer a license will supply IP to another party (the ‘licensee’). In exchange for various financial payments from the licensee to the IP owner, the owner will essentially let the licensee exploit the IP under circumstances that would, absent the license, be illegal. These transactions are required for patents since a patent does not give its owner unfettered right to practice the invention, only the right to exclude others from practicing the invention. Thus, a patent owner may wish to license others to generate income or others may require a license in order to legally practice a particular invention. Therein lies the need for a document describing the transaction between a licensor and licensee.

In the case of drug companies it may take many years for the company to produce a new medicine and, therefore, to make profits. This is why up-front payments from a licensee are important. However, when they come, profits can be enormous. The usual way to share profits is through royalty payments. A royalty is a payment, usually a fixed percentage per unit sold, to an intellectual property owner

established by contract or other agreement. Royalty rates can be 'tagged' to other things besides sales, i.e., volume/weight of active ingredient or final product.

From a business viewpoint, the goal of any specific license is to eliminate the threat of litigation from either party at a cost that is commensurate with the risk eliminated. Certain considerations need to be reflected upon, and these will be different for the for-profit or non-profit partner. Only a few of these are summarized below.

- How financially stable is the recipient of the license? Under what circumstances will the return of rights be triggered?
- Does the licensee have access to the resources needed to develop and/or manufacture the product?
- Are others competing for the same rights?
- Are there other barriers to entry into the market?

## 2.5 *Distributorship Agreements*

These agreements typically are between a PPP and a licensee's distributor and involve products that, for many PPPs, are significantly "downstream" of the early-stage products that may be in the portfolio. Thus, some PPPs may not have much experience with drafting and negotiating such late-stage contracts. These agreements offer the clearest leverage point for pricing as well as an opportunity to stipulate quality requirements. Both quality and price are important determinants of "affordability".<sup>27</sup>

The PPP or owner of the IP to the product typically desires each of its distributors to develop and satisfy the demand for its products in a particular segment of trade, as discussed above for licensing agreements. In many distributorship agreements, the segment is defined by a geographical area (e.g., sales of products in the South Africa and Namibia). In other cases, and depending on the product, the segment can even be defined by the type of customer (e.g., sales of products for use by hospitals and other health care providers).

In an area of primary responsibility ("APR") clause, the distributor covenants to use its "reasonable efforts" or "best efforts" to develop and satisfy the demand for the products in a specified territory or class of trade. Performance goals may be established to aid in determining whether the distributor has met this goal for the APR. APRs of different distributors can be made to overlap, either initially or later if a distributor fails to achieve performance goals. The agreement may require that the distributor may only receive shipments from the PPP or manufacturer at specified warehouse locations, or that the distributor shall establish warehouse or resale offices only at specified locations. These restrictions can satisfy the manufacturer's desire that the distributor's efforts be concentrated in a particular geographical area, but do not preclude the distributor from making some quantities of sales elsewhere.

From a drafting standpoint, it frequently is possible to define the segment by a reservation (e.g., "Sales to the Private Sector (as defined) are excluded from Distributor's Territory under this Agreement") rather than by a negative covenant ("Distributor agrees not to sell Products to any Private Sector member"). This phrasing places emphasis on the distributor's role in the overall system of marketing the product, rather than on a restraint on "inalienable" rights of the distributor to sell to anyone it chooses. This emphasis, which can be applied to many parts of the contract, helps to confirm that the resale restrictions are imposed for the PPP's benefit and not to facilitate division of the market among a number of distributors.

Some PPPs may insist that the distributor purchase its entire requirements of a given type of products from the manufacturer. Occasionally, all that the PPP needs is to require purchase of such quantities as are required "to meet the demand for products" in the distributor's trade segment. The requirement merely ensures that the distributor buys products of the manufacturer's brand from the manufacturer, not from other resellers. The drafter may also wish to state affirmatively that the distributor is entitled to handle competing goods, subject to any performance goals.

The distributor agreement frequently specifies performance goals. These goals are most often expressed in terms of sales volume or revenues. The drafter should carefully consider the purposes of the goals and the specific consequences of the distributor not meeting them. It may be sufficient to use the goals

as one important part of a periodic review between PPP and distributor to determine whether the distributor is performing satisfactorily, so that the PPP can determine whether to renew the arrangement. In this manner, the PPP can use any shortfall as leverage to negotiate remedial measures for the following year. Rather than declaring that failure to meet performance goals is grounds for immediate termination, the drafter should consider permitting the manufacturer to convert an exclusive territory to a non-exclusive, or to give other distributors an overlapping APR. These provisions are less onerous and less likely to provoke litigation, since the distributor is free to continue selling the products.

As with license agreement much further “upstream”, agreements regulating the distributor’s minimum resale price levels remain problematic. One can affirmatively state that the distributor’s resale prices are for the distributor alone to determine. By clearly announcing this rule, the drafter may help to keep the PPP’s own personnel from making statements, and other distributors from registering complaints, that could be inferred as attempts to regulate resale prices.

In the context of the present discussion, all parties to these agreements have a legitimate interest in ensuring that price reductions are passed through to the end user (i.e., the consumer) rather than being retained by the distributor.

## 2.5 “Non-legal” agreements

### 2.5.1 Letters of intent

*Letters of intent* (LOI) are preliminary agreements that state proposed terms for a final contract and serve to facilitate negotiation of complex deals. However, courts in the USA, have found letters of intent to be binding as a contract even though both parties may not have intended them to be legally binding. This is usually because of language such as “agreement in principal” or “memorandum of intent,” or the charging of non-refundable fees. An LOI focuses the parties on the material terms of the proposed transaction. It evidences some commitment by the parties to go forward with additional time, effort and expense knowing that they have initially established a basis upon which the deal could be done. An LOI also provides some measure of “moral commitment” as well – issues traded for should not be retraded. On the downside, the LOI may get so detained and overly negotiated that it is as expensive and time-consuming as the definitive agreement, but lacks enforceability. The LOI should not establish any agreement as to the terms of the proposed transaction, it should not consummate any transaction, nor should it obligate the parties to enter into any definitive agreement. The terms of the proposed transaction as expressed in the LOI should be expressly stated to be nonbinding.

### 2.5.2 Letters of Collection (LOC)

The National Cancer Institute’s letters of collection (LOC) includes some explicit legally binding provisions although it uses terms like ‘will make best efforts’ rather than ‘will require’ because it is the policy of the National Institutes of Health (NIH) Patent Policy Board to defer negotiations and agreement upon a specific royalty rate until the specific invention is ascertained.

The NCI LOC states, in part that their role in any collaboration with a ‘source country’ includes very broad language, entirely suitable for such an early-stage and speculative collaboration:

The DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to [SCI],

subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.

Should the agent eventually be licensed to a pharmaceutical company for production and marketing, ... NCI will require the successful licensee to negotiate and enter into agreement(s) ... as appropriate. This agreement(s) will address the concern ... that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate...

28

Under US patent law if contributions by collectors of the source material outside of the United States are not written down, dated, and signed they cannot be considered “inventions”.

## **2.6 Agreements from Other Disciplines that may have bearing on “affordability” language (See also Chapter 3)**

### **2.6.1 Humanitarian Use Licensing in Agriculture**

Under certain circumstances technology suppliers have been willing to transfer a technology without receiving a license or royalty payment as long as a contractual strategy for segmenting markets is designed. This can be useful in agriculture and there are examples of such *humanitarian use licensing* contracts. In this type of contract, agricultural multinational corporations or Universities transfer their proprietary technology to poor farmers organised in general by local governments, without requesting the payment of a royalty. Humanitarian use licensing contracts are generally to the users to whom it is donated and thus they tend to segment international markets- a situation, which may be more likely to occur in agriculture than in the pharmaceutical sector.<sup>29</sup> This specificity implies that the transferred technology cannot be used in another place, so there is limited risk of losing property rights. Such inaccessibility is more difficult for the pharmaceutical sector but it is not impossible and geographic and product restrictions are often “built into” license agreements.

### **2.6.2 “White Knight” and Benefit Sharing Agreements**

“White knight” clauses have been used in contracts to provide for the establishment of a benefit flowing from the technology supplier or user to the local community.<sup>30</sup> For genetic material or final products derived from natural products, the Convention on Biological Diversity (refs) provides for “benefit sharing” between the indigenous population and the exploiter of the natural material.<sup>31</sup> There is a large literature on the use of “benefit sharing” these agreements for use of genetic resources and natural products.<sup>32</sup> For example, some portion of upfront royalty payment or some fraction of the royalty stream might go into a community trust fund to help offset the financial handicap of indigenous peoples regarding access to legal assistance and litigation. Up-front payments and advance payments, which are often made to the supplier of information soon after a contract is signed, might also go to setting up health clinic or other community intervention. Whether or not such agreements have actually made a difference to the communities whose resources have been expropriated is open to debate.<sup>32</sup>

## **3. What is “affordability”?**

Consider this contract language (abstracted from a sponsored research and development agreement):

“ \_\_\_ hereby grants to \_\_\_ a royalty-free, non-exclusive license [and sublicense] in the “Developing Countries” [defined in either a pre-set list or defined by national economic indicators...] under the IP for treating [condition X] to develop, make, [have made], use, sell

and import the Product for the sole non-commercial purpose of making such Product *readily available and affordable* in the public sector of the 'Developing Countries'..." (emphasis added).  
What does "readily available and affordable" mean?

A useful working definition of "affordability" means that a licensee must provide the product at prices that patients can afford, or retain the right to limit the price of the products when sold. However, it may be especially difficult to get companies to agree to conditions regarding prices, even if applied only to developing countries. On the other hand, price is an easily measurable condition that could be easier to implement than, for example, broadly defined requirements about access. In fact, "affordability" of medicines can comprise several components relevant to this discussion, availability and access.<sup>27</sup>

- Availability- i.e., whether a satisfactory product has been developed. Accessibility- Ensuring quality, rational selection, appropriate prescribing and use.
- "Access"- The effectiveness of the drug distribution system and factors such as reimbursement (if any), procurement, financing, the knowledge and 'health-seeking' behavior of end-users are typically outside the control of product development PPPs and are likely to remain so. Responsibility for assuring most of these rests with governments.

A recent example illustrates the commercial pressures on for-profit companies and how such pressures will affect negotiations, even for medicines whose only market is in developing countries. Novartis, the Swiss pharmaceuticals company that manufactures the drug Coartem®, has demanded that the World Health Organization provide it with binding three-year contracts to purchase its medicines. This is a distinct change from 2001 where Novartis pledged to provide Coartem® "affordably" but forecast demand for its drug has grown well beyond the original predictions made by the WHO. Novartis is not willing to maintain its commitment to the offer without some degree of financial certainty about purchases to justify the investment it will make in several factories. Novartis controls about 60 per cent of current global production<sup>33</sup>.

### ***What aspects of "affordability" access are under PPP influence?***

**What aspects of access to medicines are under (some) control of product development partnerships?**<sup>34</sup>

Strong control:

- The choice of which candidate products to develop;
- Stability/storage shelf life, distribution difficulty, ease of administration and likely compliance: all factors in "access"
- The choice of development partners
- Whether to seek regulatory approval as a product sponsor, or to leave this to the chosen manufacturer
- Populations targeted for preferential supply, i.e., countries, markets
- Specifying ownership of IP (all types) generated during the agreement (i.e., leveraging its investments)
- Investigating studies relevant to developing countries such as co-administration and safety in malnourished groups, efficacy in pregnancy, etc.

Weaker control:

- Manufacturing costs - cannot alter cost of goods if difficult to manufacture
- Price charged (to some degree through 'cost-plus' conditions)

No effective control

- Health systems issues
  - Reach of health services
  - Staffing of health services
  - Competence of health personnel
  - Efficiency of health services/product distribution
  - Public/private mix in health services, which can affect quality of care
  - Procurement practices and efficiency

- Allocation of resources for health systems
- Allocation of government resources for product purchase
- Purchasing power of consumers
- National policies regarding product choice and drug policy, and the speed of their formulation
- Policy recommendations of international agencies and the speed of their formulation

Indeed, in most licensing agreements, there are no conditions with respect to price of the final product since the licensor will take it for granted that the recipient of the license or technology transfer knows the best price to get the best return on the investment.<sup>35</sup> For product PPPs, the price for the final product could be stipulated in advance, although this is also contingent upon either, or both, parties knowing IN ADVANCE technical details of the production, marketing and distribution costs. Because originator drug companies do not disclose production costs, it may be difficult to specify such costs in the absence of a competitive generic market.<sup>36</sup> As many PPPs have only early stage technology, specifically stipulating price in a contract is a risky proposition. The price could be implied, i.e., the cost of final product could be the cost of production (assuming one or both parties knows this), plus some reasonable mark up that is negotiated in advance.

For drugs only supplied to low-income markets, products could be priced at average cost; in contrast, for drugs sold in both high- and low-income markets, products for the poorer countries could be priced at marginal cost, since profits from higher income markets could cover fixed costs.<sup>35,36</sup> Prices could include income-adjusted margins for countries with greater ability to pay, such as lower- and upper-middle income countries. Given the dynamic nature of production costs, it would be extremely difficult to calculate costs quickly and consistently.<sup>37</sup>

Textbox 1: "Cost plus" pricing language

"... \_\_\_ agrees to use commercially reasonable efforts to manufacture or have the Product manufactured and supplied in reasonable quantities for sale or distribution to the Public Sector (as defined) of one or more Developing Countries (as defined) and at prices that do not exceed \_\_\_\_'s actual incremental costs of production and other costs which would not have been incurred but for such production... plus a reasonable profit to be agreed upon... the 'reasonable profit' shall take into account the need for the Product to be affordable in Developing Countries and the ability of \_\_\_ to otherwise generate a profit in markets outside of the Public Sector in the Developing Countries."

Note: If this is an exclusive license agreement, then failure to meet these obligations regarding quantities or price within a certain period and after an opportunity to "cure" the problem will trigger provisions that allow other entities to make the product.

## Textbox 2: Implied Pricing Requirements

X (licensee) shall purchase the Product exclusively from Y (licensor). Product shall be supplied to X in finished market packs Ex Works the manufacturing facility designated by Y. Y shall advise X of a minimum batch size for the manufacture and supply of each dosage strength of Product. X shall provide quarterly forecast updates on a rolling \*\*\* basis to Y. The \*\*\* of such forecast will be binding. In the event of a failure to supply (to be defined) by Y, Y shall grant to X a production license to manufacture the Product.

**PRICE OF PRODUCT** The price to be charged by Y to X for the supply of Product for commercial sale in the Territory shall be:

- \*\*\*% of Net Sales Price (NSP) for the \*\*\* \*\*\* for Product in the Territory;
- - \*\*\*% of NSP for the \*\*\* \*\*\* for Product in the Territory; and
- - \*\*\*% of NSP for \*\*\* during the Term of the Agreement.
- 

NSP shall mean in the case of Product sold by X or an affiliate, that sum determined by \*\*\* \*\*\* for the Product by X or, its affiliate, as the case may be, in accordance with standard accounting principles, a maximum deduction of \*\*\*% to cover the following:-

Market shall mean the sale of the Product in the Territory by X or its Affiliates, to an unaffiliated third party, including but not limited to a wholesaler, chain store, distributor, managed care organization, hospital or pharmacy.

## Text Box # 4 NIH/BMS license for ddi

Paragraph 3.2 permits the government to issue additional licenses if BMS cannot demonstrate, with evidence, that there is a reasonable relationship between the pricing of ddi and the health and safety needs of the public.

3.2 LICENSEE acknowledges the concern of the Government that there be a reasonable relationship between LICENSEE's pricing of Licensed Product and the health and safety needs of the public and that this relationship be supported by evidence. If, during the exclusive marketing term of this Agreement, as provided under Paragraph 2.1 above, LICENSEE fails to provide such evidence upon reasonable request of the Director, Division of Cancer Treatment, National Cancer Institute, NTIS has the right to require LICENSEE to grant sublicenses under Licensed Patent(s) to responsible applicants on reasonable terms when necessary to fulfil health and safety need. It is agreed that such evidence will be treated in a confidential manner. Any requirement to grant sublicenses shall be deemed a modification of this agreement...

These license terms notwithstanding, the experience of the NIH on negotiation of license terms containing “reasonable pricing” provisions was negative. Soon after the NIH policy of ‘reasonable pricing’ was introduced,<sup>38</sup> industry objected as they believe this was a form of price control. Industry, in effect, stopped dealing with NIH and in 1995, this policy was revoked.

It is possible to relate essential drug prices to development indicators, such as per capita GDP, the United Nations Human Development Index (HDI), or World Bank low and middle income country] classifications.<sup>39</sup> Merck and Roche also offer their ARVs at different prices to developing countries based on several criteria, including rank on the HDI, adult HIV prevalence rate, location in sub-Saharan Africa, classification as an LDC, and/or classification by the World Bank as low or lower middle income.<sup>40</sup> However, grading drug prices by national data such as per capita income is inequitable, as intra-country social/economic gradients are not taken into account. Differential pricing does not factor in levels of health expenditure per capita, disease burden, or urgency of the relevant public health problem—all affecting ability to pay.

Generally, therefore, it is difficult to try to set a specific, fixed price for a drug that could be considered globally and objectively “fair, equitable, and affordable.” Rather, ideally, assessments of what constitutes an affordable price should be made on a country-specific case-by-case basis, taking into account a number of public health factors, including:

1. Epidemiology of the disease:
  - a. Who is affected? (e.g. children, rural areas, pregnant women, general population)
  - b. What is the prevalence?
  - c. What is the incidence? (e.g. How infectious is the disease?)
  - d. How urgently does the individual need the drug? (e.g. is it a fast-acting debilitating illness, or slowly developing condition?)
2. Purchasing power of the affected population
3. Capacity of the government either to provide or subsidize the drug for the those who cannot afford it, taking into account:
  - a. Current national level of health and drug expenditure per capita
  - b. Availability of special long-term funding (e.g. from a committed donor)
4. The cost of any alternative existing treatment (i.e. a substitute)
5. Estimated benefits—both individual and at community level— resulting from access to the drug<sup>39</sup>.

## Text Box #5 Combination Products and Pricing Stipulations:

\_\_\_\_\_ will not require the payment of royalties or similar charges in relation to any of the above licenses in excess of five per cent (5%) of the net sales of the relevant antiretrovirals (and for this purpose "net sales" shall mean the total amount invoiced or otherwise due (after deduction of all taxes and discounts as shall be agreed between the licensor and the licensee at the inception of the license agreement) on sales by the licensee to third parties in terms of the relevant license) — provided that, where a product sold contains zidovudine and/or lamivudine in combination with one or more other antiretroviral drug(s), the aforesaid maximum of 5% shall be reduced proportionally by means of the formula:

$Z+L/Z+L+X \times 5 = \text{applicable maximum \%}$   
where

(a) Z = 1 where zidovudine is contained in the product and 0 where zidovudine is not contained in the product;

(b) L = 1 where lamivudine is contained in the product and 0 where lamivudine is not contained in the product;

(c) X = the number of other antiretroviral drugs contained in the product (and, for the avoidance of doubt, it is recorded that the generic equivalent of Combivir® would attract a maximum royalty or similar charge of 5% of net sales);

### 3.1 Using “access” as a proxy for “affordability”

Many organizations attempt to provide “access” to insure that any final product financed in whole or in part by PPP monies is made, use, sold or imported into specified countries, and not just in the established market economies. A number of indicators can be used to measure whether access is being achieved<sup>27</sup> and these could be stipulated in the contract, although this imposes administrative and transaction costs to track this.

## Text Box # 6

In the event that the research conducted under this agreement leading... to a viable product for control of \_\_\_\_\_, and licensee has not continued development of a product or, after receiving regulatory approval, has not continued marketing such product in [any country, list of countries etc.], PPP may request licensee continue developing or marketing, as the case may be. If, after a notice and ‘cure’ period, licensee elects not to continue development or marketing, licensor shall continue development or marketing itself. Licensor may also grant royalty-free, sublicenseable and non-exclusive licenses under all IP pursuant to this agreement to third parties \_\_\_\_, provided that such IP is reasonably necessary for the development, manufacture and sale of such product for control of \_\_\_\_\_.

Another way to measure when something like voluntary licenses were triggered would be to develop an access metric that would for example, trigger non-exclusive licensing or patent revocation where:

- A significant population that would benefit from an invention does not have access to it because the price of the product is too high.
- The licensee of the product is charging prices that differ significantly from marginal cost.

- The product is priced excessively, even to patients who get the product.
- Patents block research and development of other products.<sup>36</sup>

### 3.1.1 Field of use reservations.

There are many examples of language “carving out” specific technical fields, to be divided up among the various licensees and the licensor. An example (with some details changed) is illustrated in Text Box #7.

Text Box # 7 License Grant to LICENSEE.

PPP hereby grants to LICENSEE an exclusive license, including the right to grant sublicenses, under the IP Rights to develop, make, have made, use, sell, license, market and otherwise exploit Products in the Territory. Except as set forth below... such license to Licensee shall be exclusive to LICENSEE. Such license to LICENSEE shall be limited to the LICENSEE Field as defined below ....

Reservation of Certain Rights. The license granted to LICENSEE by the Agreement is subject to the reservation of (a) a non-exclusive license, with the right to sublicense, for PPP to develop, make, have made, use, sell, license, market and otherwise exploit Products claimed by the IP Rights solely for commercial use in the “PPP Field”, as defined below....

Note: “LICENSEE Field” is defined as the TB diagnostic market. “PPP Field” is defined as the TB treatment market.

### 3.1.2 Territory restrictions

A PPP can reserve options for developing countries and pose requirements for further development by others depending on various circumstances. The basic stipulation is: \_\_\_ hereby grants to \_\_\_ a royalty-free, non-exclusive license [and sublicense] in the “Developing Countries” [either a pre-set list or defined by national economic indicators...] under the IP for treating [condition X]...”

It is difficult to price “affordability”. For a non-profit PPP the challenge is to come up with drug that can be incorporated into the existing price structure. For TB, full treatment can range from about \$10 to about \$40 for 6-9 month course of treatment. Moreover, if the intent of the PPP is NOT to make money, and the expectation is that “nobody makes money on this arrangement”, structuring such an arrangement can become complex if there is a for-profit partner.

Text Box #8

Subject to the terms and conditions of this Agreement, THE PPP grants to the LICENSEE a nontransferable, royalty-bearing license to make, have made, import, use, and sell Licensed Products covered by the Licensed Patents in the Exclusive Territory as specified in Exhibit B where patent rights exist.

THE PPP reserves the right to use the PPP IP rights and associated technology for non-commercial, educational, and research purposes.

The PPP also grants to LICENSEE the right to issue royalty-bearing sublicenses to third parties to make, have made, import, use, and sell Licensed Products in the Exclusive Territory, provided LICENSEE has current exclusive rights under this Agreement at the time of such sublicenses. LICENSEE must sublicense in the Exclusive Territory if LICENSEE cannot adequately supply market requirements.

An interesting license grant allows sublicenses in different institutions in different countries so that there is a multiprong approach to insure success in terms of non-exclusive licensees. In principle, if the Brazilian effort fails and the Indians succeed, India can sell in Brazil as well. This can be created with many variations.

Text Box #9

A. Subject to the terms and conditions of this Agreement, PPP grants to the LICENSEE an exclusive license to make, import, use, and sell Licensed Products covered by the Licensed IP in the United States and the European Union in the Field-of-Use, as specified in Exhibit B where patent rights exist.

B. The PPP also grants to LICENSEE a non-exclusive license to make, import, have made use, and sell Licensed Products in the Field-of-Use in Brazil, India, and China. This non-exclusive license stipulated in Section B has the following conditions:

1. The non-exclusive license for Brazil requires that \_\_\_\_\_ be the sole sublicensee and that such license is for use in Brazil only.
2. The non-exclusive license for India requires that \_\_\_\_ and \_\_\_\_ be the sole sublicensees for India as well as Southeast Asia (countries as defined).
3. The non-exclusive license for China does not require any particular sub-licensee.

The existence of multiple, non-exclusive licensees in developing countries may, or may not, be sufficient to lower prices due to competition. In this regard, PPPs should be aware that licensees in this situation might begin to try and protect themselves by attempting to introduce a 'most favored licensee' (MFL) clause into PPP agreements. In effect, an MFL clause stipulates that if a grant to a third party licensee for the same product and under the same IP, is under "more favourable" terms, then the first licensee is entitled to the more favourable economic terms.

### 3.1.2.1 Within country targets

Even though licensor X may not care about public sector sales in country X, they might very well care about sales in the private sector. Complex interactions are at work. In countries that have a very limited, nascent private sector, a multi-lateral supported program that focused exclusively on the public sector could potentially crowd the private sector out of health care altogether. Alternatively, in countries that have substantial and relatively unregulated private sectors, channelling multilateral resources to private providers might exacerbate problems of inappropriate growth and behavior within the private sector. Nonetheless, segmentation of markets within countries (into public and private) is becoming an issue. Indeed, within each country, the public/private sector allocation may be different for different conditions, e.g., TB and malaria might have different mixes of public and private sector sales.

Text Box # 10

PPP hereby grants to the Licensee the right to make, use, sell, market, and distribute Product in the Territory under IP Rights furnished by PPP to the Licensee. This license shall be exclusive to only PPP and Licensee for private sector distribution and fully non-exclusive for public sector distribution.

Licensee shall have the right to use one or more distributors for distribution of Product in the Territory under this license, provided: that PPP has received a draft of the proposed distribution agreement and has given prior written approval of its terms and that the terms and stipulations of this License are consistent with the terms of the proposed distribution agreement, particularly with regard to obligations of public sector distribution.

In all these various types of “carve outs” of territories and fields of use, careful definitions are essential. In principle, such limitations could take advantage of market segmentation, either by instituting different licensing terms for different consumers of the same product (with reduced or no royalties for the poorest), or by applying very favorable licensing terms to certain classes of products. In the latter case, the “carve out” would apply to products for diseases whose burden is only found in developing countries. This, however, could be complicated by the fact that the disease burden in developing countries is shifting toward chronic diseases such as heart disease and diabetes, which are also represent a large drug market in industrialized countries.

Furthermore, “leakage” of the technology from public to private sectors (and vice versa) is probably unavoidable. In terms of lost markets for the licensee, the question is how many in the public sector (e.g., government procurement agencies, even patients) would have purchased the medicine from the private sector had they not been granted preferred access via the license. In India, for instance, most patients go to the private sector for treatment. Indeed, this would appear to be a big practical hurdle for such license terms as many developing countries have a growing private sector so that market segmentation must also be within the country. This is a difficult legal and administrative challenge. Defining a target mechanism to minimize leakage would be essential.<sup>41 42</sup>

Text Box # 11 **Setting** Performance Milestones to Ensure "Affordability"

**Developing Country:** means countries eligible for support from the \_\_\_\_\_ PPP or foundation, which at the effective date of this **Agreement** are those countries with a Gross National Product of less than US \$1,000 per capita per year, and at the effective date of this **Agreement** include the countries designated in Appendix F of this **Agreement**.

Upon **First Commercial Sale** in the U.S., **Licensee** or sublicensee will provide the people of [Country] who are infected with HIV with **Licensed Product** at no cost and upon request of [that Country's] Government.

**Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify Licensor that the **Benchmark** has been achieved.

1. Begin negotiations for an agreement with the Government of [Country] as to the extent of benefit return to [that Country] from eventual marketing of synthetic **Licensed Product** within one (1) month of the **Effective Date** of the **Agreement**. Complete agreement with [Country] within nine (9) months of the **Effective Date** of the **Agreement**.

a) To the extent that **Licensee** shall satisfy the potential **Public Sector** market through its own resources, **Licensee** shall deliver the first allotment of a safe and effective drug to the **Public Sector** for distribution and/or sale in **Developing Countries** within two (2) years of **First Commercial Sale** and thereafter **Licensee** agrees to use commercially reasonable efforts to meet any delivery date and in the quantities required in an order placed by the **Public Sector**.

b) To the extent that **Licensee** shall satisfy the potential **Public Sector** market through joint ventures with third parties, **Licensee** shall:

1) Within one (1) year after **First Commercial Sale**, make reasonable efforts to negotiate with third parties in order to effect joint ventures or other partnership agreements to make and sell the **Licensed Products** and **Licensed Processes** and to provide know-how and effect technology transfer to said third parties that will allow them to manufacture a safe and effective drug for distribution and/or sale in **Developing Countries**.

2) Within two (2) years of **First Commercial Sale**, have entered into at least one joint venture or other partnership agreement with at least one third party for the purpose of manufacturing a safe and effective drug for distribution and/or sale in **Developing Countries**.

3) Within four (4) years of **First Commercial Sale**, ensure that said third party (ies) have delivered a first allotment of a safe and effective drug to the **Public Sector** for distribution and/or sale in **Developing Countries**, and thereafter ensure that said third party (ies) use commercially reasonable efforts to meet any delivery date(s) and in the quantities required in an order placed by the **Public Sector**.

### 3.2 *White knight clauses and other "benefit sharing" statements*

So-called "white knight clauses" are closely related to "benefit sharing" agreements of the Convention on Biological Diversity. White knight clauses have been developed by the National Institutes of Health (Maria Freire, personal communication, November 2004). For the NIH, when an organization enters into an agreement for a product where there is a market in a developing country, as part of payback to tax payers for taking on a technology made with taxpayer funds, the organization must provide some public benefit as part of license. However - if there is not a market, or the technology is in the early

stages (as it always is with the NIH)- specifically requesting a “benefit plan” when the identity and utility of the product is unknown, is probably not worth the effort. A contingency clause might be one of terms of the license, so that when the organization does get market approval in a developed country, they will be required to provide “benefit plan” at that time. Requirements for benefit sharing can include <sup>43</sup>:

- Supply back of Licensed Products or Services
- Health education programs (web or print)
- Indigent access programs for Licensed Products
- Biodiversity compliance for natural products
- Developing country access for Licensed Products
- Acknowledgment in publication
- Joint research and increased scientific capacity;
- Participation in planning and decision-making
- Control over samples and research results
- Co- ownership or sole ownership of intellectual property rights
- Commitment to re-supply in source country
- Free access to technology and products resulting from the agreement
- Technology transfer (equipment and material donation)

### **3.3 *Non suit agreements***

A “non suit” agreement in the present context is an agreement that an IP holder will not assert these IP rights against one or more parties to the agreement. One PPP has made creative use of non-suit agreements. The PPP did not wish to pay large up-front contract payments but promised the IP holder that by phase III, the PPP would negotiate a commercial license in good faith. This agreement contained a statement protecting the PPP from past patent infringement (a so-called “release”) and also a covenant not to sue going forward until phase III was reached. This particular non-suit agreement was relatively straightforward and, in principle, these sorts of agreements or covenants not-to-sue may offer an alternative to the sorts of licensing language discussed above.

## Text Box # 12

A. \_\_\_\_\_ undertakes that no affiliate of \_\_\_ company will enforce any relevant patent or any equivalent patent of any \_\_\_ affiliate in any of the countries listed in Annex 1 against conduct of a licensee complying with any license or extension of a license contemplated in this agreement.

B. IP owner on behalf of itself and any successors-in-interest to Patent No. \_\_\_\_\_ (“the \_\_\_\_\_ patent”) hereby unconditionally and irrevocably covenants (1) not to assert any claim of patent infringement (including direct infringement, contributory infringement, and inducing infringement) against \_\_\_\_\_ under the \_\_\_\_\_ patent as it currently reads; and (2) not to assert the \_\_\_\_\_ patent as it currently reads against \_\_\_\_\_ as a basis to recover royalties under such \_\_\_\_\_’s license agreement with IP holder. This covenant covers any and all methods, processes, and products made, used, offered for sale, sold, or imported by \_\_\_\_\_ at any time, whether before or after the date of this covenant. As used in this covenant, “products” broadly includes \_\_\_\_\_ and any other thing that would infringe any claim of the \_\_\_\_\_ patent as it currently reads. This covenant covers all claims in the \_\_\_\_\_ patent as they currently read, and any claim in any reissued or reexamined version of the \_\_\_\_\_ patent that is the same as, or substantially identical to, any claim of the \_\_\_\_\_ patent as it currently reads.

C. \_\_\_\_\_, on behalf of itself and any successors-in-interest to United States Patent No. \_\_\_\_\_ hereby unconditionally and irrevocably covenants (1) not to assert any claim of patent infringement (including direct infringement, contributory infringement, and inducing infringement) against \_\_\_\_\_ (collectively, “plaintiffs”) under the patent as it currently reads; and (2) not to assert the patent as it currently reads against any plaintiff as a basis to recover royalties under such plaintiff’s license agreement with \_\_\_\_\_. This covenant covers any and all methods, processes, and products made, used, offered for sale, sold, or imported by any plaintiff at any time, whether before or after the date of this covenant. As used in this covenant, “products” broadly includes ... This covenant covers all claims in the patent as they currently read, and any claim in any reissued or reexamined version of the patent that is the same as, or substantially identical to, any claim of the patent as it currently reads. The term “substantially identical” as used herein is intended to have the same meaning as that term is used in \_\_\_\_\_.

This covenant does not extend to (1) any claim in any reissued or reexamined version of the patent that is not the same as, or substantially identical to, any claim of the patent as it currently reads; (2) any claim in any patent that may issue from United States Patent Application No. \_\_\_\_\_; or (3) any claim in any other patent, whether related or unrelated to the patent. In addition, this covenant does not extend to any affiliate or customer of any plaintiff.

### 3.3.1. Non-suits, market segmentation and parallel trade

Although not unique to non-suit agreements, questions having to do with discriminating between, and defining, “non-suit” countries and those where the IP will be defended will continue to plague negotiations.

Consider the following draft language (not found in any agreement of which we are aware). One can immediately see the difficulties in trying to distinguish between “non-suit” countries, and even between for-profit/non-profit entities within countries. <sup>a</sup> Indeed, the issue of parallel trade, pharmaceutical arbitrage and using trade dress to distinguish between goods destined for “non-suit” countries (paragraph 3, below) will be difficult, but not impossible, to manage.

Textbox # 13

The Licensor and Licensee (as defined herein) on behalf of themselves and any successors-in-interest to the Intellectual Property (as defined herein) covenant that they will not, before or after the date of this Covenant, assert any claim of patent infringement (including direct infringement, contributory infringement, and inducing infringement) under the Intellectual Property for manufacture, use, sale, offer for sale or importation, subject to the following conditions:

1. Any manufacturing, use, sale, offer for sale, importation, must be in, or into, “Covenant countries”
2. Any manufacturing, use, sale, offer for sale, importation, must be for only “public sector entities” in said Covenant countries
3. Any Licensed Product for manufacture, sale, offer for sale or importation under this Covenant must be labelled, marked, and otherwise by Licensee to distinguish itself from:
  - a. Licensed Product that is made, sold, offered for sale, imported in, or into, “Non Covenant Countries” and
  - b. Licensed Product that is made, sold, offered for sale, imported into and for, the “private sector” in Covenant Countries

For avoidance of doubt, this Covenant does not extend to (1) any claim in any reissued or re-examined version of IP that is not the same as, or substantially identical to, any claim of the IP as it currently reads; (2) any claim in any patent that is not part of the IP; 3: any manufacture, sale, use, offer for sale or importation in, or into, any “Non Covenant” whether public sector entities or not, (4) any IP owned by a third party to which Licensor has no ability to further license

Discussion of price discrimination and parallel trade is beyond the subject of this document. I note, in passing, that all contract language that divides markets on the basis of disease, economics/ability to pay, ‘non-assertion’ of IP and so on, depends, on lack of arbitrage or leakage between segments. <sup>44</sup> The threat of parallel imports undermines the ability to segment markets by country. <sup>44</sup>

These issues have been all discussed in one forum or another. A successful non-suit covenant in the present context will mean that a patent holder would not enforce IP against a manufacturer that makes, and a distributor that sells, cheap copies of urgently needed drugs in the public sector of poor countries. The manufacturers would not have to be located in developing countries, but could be anywhere in the world provided the non-suit is granted on condition that the producer supplies products only to the “private sector” in “Covenant countries”. Generics companies could compete on price, but would not compete with the patent owner in “non-Covenant” countries. The risk of parallel trading of medicines from “Covenant” countries to ‘non-Covenant’ countries would be diminished by stipulating different shapes and colors from the product sold in countries where IP is asserted.

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<sup>a</sup> The intention is that IP would be asserted against “for profit” entities (e.g., private buyers; corporate purchasers) even within a “Covenant” country but that “non profits” (charitable purchasers and government purchasers) would not have IP asserted against them.

## 4. Summary

Intellectual property issues are part-and-parcel of the risk inherent in pharmaceutical R&D. Stewart Brand, a noted thinker on knowledge and information creation and management, is much quoted by proponents of “open source” computer software as saying “Information wants to be free because it has become so cheap to distribute, copy, and recombine--too cheap to meter.”<sup>45</sup> This quote is incomplete. He next said, “ It [also] wants to be expensive because it can be immeasurably valuable.... That tension will not go away. It leads to endless wrenching debate about price, copyright, intellectual property, and the moral rightness of casual distribution, because each round of new devices makes the tension worse, not better.”

Through various intellectual property contract provisions, product development partnerships, as currently constituted, have a capacity to ensure access by individuals in poor populations to any products that may emerge from their efforts but this capacity is limited.<sup>34</sup> The fact that most product development PPPs are too far “upstream” in the product development process and “affordability” may better be exploited through interactions with “downstream” regulatory, financing, distribution and end user relationships.<sup>34</sup> Further, explicit stipulation of prices in PPP contracts raises anti-trust issues. Although the language used in contracts to ensure ‘affordability’ is limited only by the creativity of the collaborators and the context and culture of the agreement, there is no “magic language”. Reviewing contract language in isolation is misleading and possibly not very useful.

Consider the following “research agenda”.<sup>46</sup> Answers and solutions to these questions will allow clearer focus on these issues of “affordability” and whether contract language can really effectively influence “affordability” of medicines:

- What are the categories of product PPP subject matter for which intellectual property rights are licensed or may be licensed in the future?
- What are the terms of such licenses (including exclusivity versus non-exclusivity, royalty rates, fields of use restrictions, etc.), and who are the parties to such agreements?
- What are the structures for such licensing arrangements (e.g., cross-licensing, block or blanket licenses, compulsory licenses, etc.)?
- What are the structures and operation of patent pools among product PPPs?
- How are the planning, content, and progress of PPP R&D affected by refusals to license or offers to license on unacceptable terms?
- Does an open source model of licensing increase “affordability”?
- Are intellectual property rights involving product PPPs to which licensing arrangements pertain more or less likely to be involved in infringement litigation?

Moreover, conventional licensing practices and contract language may not necessarily result in **equitable access** to a product. Even the lowest prices charged may not be affordable. The gap between what can be done and what really needs to be done with regard to “neglected diseases” is forcing people who set policies and administer programs to provide medicines in high-burden countries, to deal with difficult questions of distributive justice.<sup>47</sup> All manner of explicit and implicit choices outside of legal agreements with PPPs regarding the pricing of medicines, patient populations, the spatial distribution of treatment centers, and other measures will determine who will get access to treatment and who will die. A well-thought out contract is necessary, but insufficient, to make sure that all stakeholders respect human rights norms and ethical standards.<sup>48</sup>

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