Annex 1
Cost Benefit Analysis for UNITAID Patent Pool[2]

20 June 2008

Introduction

The feasibility and sustainability of treatment for HIV/AIDS in developing countries will depend upon the ability of donors and developing country governments to obtain an inexpensive supply of new medicines, including those that are adapted or designed to address the health needs of people living in developing countries. The following analysis examines the costs and benefits of a UNTAID Patent Pool focusing the open licensing of inventions used for the treatment of HIV/ AIDS. Specifically, the analysis compares the estimated $1.5 million annual cost of operating such a pool to the benefits as measured by expected lower prices for second line and second generation AIDS drugs. These lower prices are expected to flow from a greater degree of generic competition, as a consequence of enhanced global norms in favor of open licensing, and by measures that make the open licensing of inventions easier, less costly and more compelling for patent owners.

As noted in the report, there are limits to this analysis. Most importantly, the UNITAID Patent Pool is designed and expected to improve the management of patent portfolios so that the competitive sector can develop better manufacturing processes, new fixed dose combinations (FDCs) or other improvements in delivery methods, such as simplified dosing, heat stabilization of products, oral delivery of injectable treatments, and the development of appropriate formulations such as triple FDCs, FDCs for Preventing Mother-to-Child Transmission (PMTCT) of HIV, and pediatric formulations. These important benefits are noted but not quantified in this analysis.

First and Second Treatments for AIDS

In HIV/ AIDS treatment a "first line" regime is the initial treatment regime given to a patient. While the first line regime would ideally be chosen strictly upon medical criteria, in practice, particularly in developing countries, it may also be based on the price. A "second line" regime is used when a patient fails on their first line regime, commonly due to the development of resistance. This requires the patient to change all three drugs in their first line regime. Patients who experience intolerable side effects may need to change one of the ARVs in their first line regime; this is called a first line alternative regime.

2 This report was initially prepared by James Love of Knowledge Ecology International (KEI) and finalized with contributions from several others including David Serafino and Michelle Childs of KEI, Ellen 't Hoen, Karen Day, Selina Lo and Laurent Gadot of MSF, Professor Brook Baker of Northeastern University School of Law and Frederic Martel, Kathleen Strong and Paulo Meireles of UNITAID. The views presented here are those of the author and do not necessarily reflect those of the members of the UNITAID Patent Pool Expert Group, the World Trade Organization, the World Intellectual Property Organization, the World Health Organization, UNITAID or DFID.

The terms "first generation" and "second generation" are normally used to describe older and newer treatments. Second generation products tend to have better (or different) medical properties including, lower toxicity, different delivery mechanisms (simpler dosing regimes, heat stabilization, etc.) or some other characteristics that make them attractive to patients and medical professionals alike.

In the United States, the most popular first line regime today includes a second generation ARV incorporated in a FDC. This particular FDC consists of TDF+FTC+EFV, and is a once-a-day treatment. Gilead reports that this combination is used by approximately 30 percent of U.S. patients receiving antiretroviral treatment (ART).[3] In the developing world, the most commonly used first line regime is a combination of first generation ARVs, d4T+3TC+NVP, which is available as an FDC, but is one pill to be taken twice a day. [4]

People who receive ART often have compelling medical reasons to switch to a different drug combination. Resistance to ARVs is a natural process that develops as a consequence of long term treatment. "In one of MSF's long-standing HIV/AIDS projects, in Khayelitsha, South Africa, one in five patients needs to be switched to second line therapy after five years of treatment because they have developed resistance to their initial treatment. Indeed, in wealthy countries, many people living with AIDS have changed their treatment lines four, five or even six times. With two million people on ARVs across the developing world, the need for access to newer ARV options is growing rapidly."[5]

Unfortunately, the prices for the second generation ARV medicines are far higher than the prices for the first generation ARVs now being used in developing countries. In many cases, the prices are an order of magnitude (or more) higher. These higher prices threaten the sustainability of AIDS treatment in developing countries.

Demand for Second Line AIDS Drugs

At present, approximately 3 million persons living in developing countries are receiving treatment for AIDS[6], a number that is expected to increase with expanded donor investments in treatment and improved treatment infrastructure.

According to the WHO, where data are available, 94 percent of existing patients who have access to treatment are reported to be receiving first line treatments, and six percent are receiving second line treatments. There are considerable differences between regions. For example, within Latin America and Western and Central Europe, 26 to 27 percent of the population reporting is on second line regimes. In South & Southeast Asia, only 4 percent of the reporting population is on second line regimes. In sub-Saharan Africa, only 1 percent is on second line treatments.

3 On June 13, 2008, Gilead said that 150,000 of approximately 500,000 persons on ART were using Atripla.

4 "Tenofovir (TDF) is now included as a preferred first-line NRTI, because of its efficacy, ease of use and safety profile. This is a change from the 2003 guidelines, which recommended reserving the use of TDF as part of second-line regimens." *Antiretroviral therapy for HIV infection in adults and adolescents*, 2006 Revision, WHO.

5 Need for Newer Drugs, http://www.accessmed-msf.org/main/hiv-aids/introduction-to-hivaids/need-for-newer-drugs/

6 WHO , UNAIDS, UNICEF 2008. Towards universal access: scaling up priority HIV/AIDS interventions in the health sector. Progress report 2008

Table 1: Use of First and Second Line AIDS Drugs

UNAIDS Region	First Line %	Second Line %
Caribbean	89	11
East Asia		
Eastern Europe & Central Asia	92	8
Latin America	74	26
Middle East & North Africa		
Oceania	99	1
South & South East Asia	96	4
Sub-Saharan Africa	99	1
Western and Central Europe	73	27

Source: WHO 2008 (Towards Universal Access Report)

Estimates about the future demand for second line treatments (often based on second generation medicines) are based upon incomplete data, particularly concerning the degree of compliance for those now receiving drugs. A high rate of adherence to treatment, such as the rates reported by some MSF-run programs, is not necessarily typical for the average patients receiving ART. Patients who have lower rates of compliance will develop drug resistance earlier, and become candidates for new (and often more expensive) drug regimes.

The Clinton Foundation recently estimated that, annually, at least 2 percent of patients in Africa and Asia and 4 percent of patients living in Latin America should be migrated from first line treatment to second line treatment for medical reasons.

Increased Prices for Second Generation Drugs

As noted above, in developing countries the most widely used first line treatment is based on first generation ARVs: the d4T+3TC+NVP (30mg, 150mg, 200mg) Highly Active Antiretroviral Therapy (HAART) regime. This consists of one pill with a combined 380 milligrams of active pharmaceutical ingredients (APIs), given twice a day, or 0.2774 kg of API per patient per year (PPY). This regime is now available for less than $100 per year from some generic suppliers.

Second generation products are more expensive, for several reasons.

1. All other combinations now available require larger amounts of APIs. For example, a second generation/first line treatment of TDF+FTC+EFV (300mg, 200mg, 600mg) involves 0.4015 kg per year of APIs. The second line protease inhibitor regime consisting of AZT+3TC+LPV/r (600mg, 300mg, 800mg/200mg) is 0.6935 kg of APIs per year.

2. The term “second generation” is typically given to AIDS drugs invented after Brazil changed its patent law in 1996. Prior to the creation of the Global Fund, Brazil was “making

the market" for generic ARVs, but only for the products invented before the 1996 change in the Brazil patent law.

3. As the developing country with the oldest AIDS treatment program, Brazil is the largest purchaser of second generation AIDS drugs, mostly from brand name suppliers. Brazil issued its first compulsory license on an AIDS drug, efavirenz, which is used in both first and second line treatment, in 2007. Prices in the global market for APIs are much higher for products only purchased from the patent owner in Brazil.

4. Universal access to knowledge of manufacturing processes does not exist for new products, leading to fewer competitors entering the market unless they have developed their own expertise.

5. With fewer people using second generation generic products, the economies of scale are not as good as for the widely used, older products such as d4T+3TC+NVP.

The following table shows global prices for pharmaceutical APIs for eleven ARVs.

Impact of Brazil Purchases of Generic APIs

Until the Global Fund and PEPFAR were created, the government of Brazil was the only significant purchaser of generic AIDS medicines. While many of the final products were formulated and manufactured domestically, Brazil also purchased APIs from generic manufacturers in India and China. The Brazil purchases of generic APIs had an enormous impact on the global prices for APIs. For example, the global prices of generic APIs for 3TC fell from more than $20 thousand per kilo in 1996, to less than $300 per kilo in 2004. These global price decreases not only benefited Brazil, but also created the possibility of low-cost ARV production for Africa and other countries.

When Brazil introduced patent protection for pharmaceutical products in 1996, it stopped buying generic APIs for the newer ARVs invented after 1996. This had the practical effect of creating a dual market for ARV APIs. API prices for products invented before the patent law change were much cheaper than products invented after the patent law change. The table below illustrates the difference in global API prices. Using data collected by the WHO in 2004 from ARV API suppliers, the table compares the **global** prices for APIs for eleven ARVs, based upon the patent status of the products in Brazil.

For the six products that were off-patent in Brazil, the average (low/high) price was $382/$582 per kilo for the raw APIs. For the five patented products only purchased from brand name suppliers, the average global API prices were $1,540/$2,760.

Table 2: Difference in Raw Global API prices (2004) and Patent Status in Brazil

Drug API	Low Price $ per kilo	High Price $ per kilo
Purchased as Generics in Brazil		
Didanosine (ddI)	450	850
Lamivudine (3TC)	295	480
Stavudine (d4T)	580	775
Ziodovudine (AZT)	360	510
Nevirapine (NVP)	320	475
Indinavir (IDV)	285	400
Average:	**382**	**582**
Purchased from Brand Name Manufacturers in Brazil		
Efavirenz (EFV)	1,200	1,600
Abacavir (ABC)	1,500	3,500
Lopinavir (LPV);	2,900	4,000
Nelfinavir (NFV)	900	1,400
Saquinavir (SQV)	1,200	3,300
Average:	**1,540**	**2,760**

Source: Source and Prices of Active Pharmaceutical Ingredients, WHO/HIV/AMDS.

As noted, this is an important illustration of the relationship between purchases of generic products in middle-income countries and the prices of drugs in low-income countries, and it should inform the decision of UNITAID in considering geographic coverage of the patent pool. The larger the global market for APIs, the more the investment, entry and competition by generic suppliers.

Global Prices for First and Second Generation AIDS Drugs (2007)

The difference in prices for first and second generation AIDS drugs is illustrated below. Using data from the 2007 MSF survey of AIDS drug prices, prices are presented in terms of U.S. dollars **per formulated and delivered kilo** of active pharmaceutical ingredient (API). Included in the table are eight products, including two fixed dose combinations that are widely used first generation drugs, and eight products, including three FDCs, which are important second generation drugs. *(As discussed above, the components of all of the first generation products were developed before the 1996 changes in the Brazil patent law, and have long been sold as generics in Brazil and in some other middle-income countries.)*

The first line FDC product d4T+3TC+NVP, which is the most widely used treatment in the developing world, is also highlighted as an important benchmark.

Table 3: Prices per Formulated API for First and Second Generation AIDS Drugs

Product	Category	Unit Price Brand	Unit Price Lowest	Number of Suppliers	Price Per Kilo Brand	Price per Kilo Lowest
First Generation						
AZT	All Cats	0.290	0.142	6	$967	$473
3TC	All Cats	0.095	0.059	7	$633	$393
AZT+3TC	All Cats	0.325	0.183	7	$722	$407
ddI	Cat 1	0.789	0.363	4	$1,973	$908
d4T+3TC+NVP	Cat 1	0.470	0.139	6	$1,205	$356
IDV	Cat 1	0.274	0.220	4	$685	$550
d4T	Cat 1	0.075	0.033	7	$1,875	$825
NVP	Cat 1	0.300	0.066	8	$1,500	$330
		Unweighted average:			**$1,195**	**$530**
ddI	Cat 2	0.846	0.363	4	$2,115	$908
d4T+3TC+NVP	Cat 2	0.784	0.139	6	$2,010	$356
IDV	Cat 2	0.470	0.220	4	$1,175	$550
d4T	Cat 2	0.089	0.033	7	$2,225	$825
NVP	Cat 2	0.600	0.066	8	$3,000	$330
		Unweighted average:			**$2,105**	**$594**
Second Generation						
TDF+FTC	All Cats	0.875	0.750	2	$1,750	$1,500
AZT+3TC+ABC	All Cats	1.167	0.750	5	$1,556	$1,000
ATV	Cat 1	0.484	0.484	1	$3,227	$3,227
SQV	Cat 1	0.288	0.270	3	$1,440	$1,350
LPV/r	Cat 1	0.228	0.228	3	$1,373	$1,373
NFV	Cat 1	0.293	0.277	4	$1,465	$1,385
TDF	Cat 1	0.567	0.534	4	$1,890	$1,780
EFV	Cat 1	0.650	0.506	7	$1,083	$843
		Unweighted average:			**$1,723**	**$1,557**
ATV	Cat 2	0.582	0.582	1	$3,880	$3,880
TDF+FTC+EFV	Cat 2	2.830	1.333	2	$2,573	$1,212
SQV	Cat 2	0.603	0.270	3	$3,015	$1,350
LPV/r	Cat 2	0.457	0.457	3	$2,753	$2,753
NFV	Cat 2	0.603	0.277	4	$3,015	$1,385
TDF	Cat 2	0.567	0.546	4	$1,890	$1,820
EFV	Cat 2	1.800	0.506	7	$3,000	$843
		Unweighted average			**$2,875**	**$1,892**

Source: Calculations based upon data from MSF, *Untangling the web of price reductions, 10th Edition*, July 2007, Revision September 2007.

Consistent with the theory that economies of scale, manufacturing know-how and competition are important, the lowest prices per kilo of API are available for the most widely used first generation/first line products. The highest prices are for second generation products that are sold by brand name companies under tiered pricing agreements in middle-income countries.

Patents

In the past seven years, there has been a significant increase in the number of patents on pharmaceutical inventions and other relevant fields of technology. WIPO reports the following trends in Patent Cooperation Treaty (PCT) patent filings, as measured by the number of inventions claimed.

Table 4: PCT Applications Published by Field of Technology

	2000	2001	2002	2003	2004	2005	2006	2007	Change
Instruments: Medical Technology	5998	7030	7357	8600	8889	9670	11251	12006	100%
Macromolecular	3640	4223	4545	5242	5705	6226	6515	6168	69%
Macromolecular chemistry, polymers	3690	4152	4252	4367	4365	4881	5908	5989	62%
Pharmaceuticals & Cosmetics	7384	9561	9653	9979	9488	11252	13925	14096	91%
Biotechnology	6795	9282	8996	8605	7663	7504	7422	7308	8%
Chemical Engineering	3851	4455	4767	5367	4907	4950	5685	5899	53%

Source: WIPO Statistics Database.

We have less information regarding the granting of patents in developing countries, but some data suggest that patent filings will be more extensive in developing countries than in the past. First, the WTO TRIPS Agreement came into force on January 1, 1995, and the ten-year transition period for non-LDCs expired in January 2005. Despite the fact that LDCs are not obligated by the WTO to issue or enforce patents on pharmaceutical products until 2015, and LDCs are excluded from the US 301 List, only 3 LDCs in Africa have reportedly exploited this flexibility in their national laws. The creation and strengthening of regional patent offices in Africa, combined with the creation of new, donor-funded markets for medicines in low-income countries may have also contributed to an increase in patent registrations in low-income countries. For example, Gilead sells two important AIDS drugs: TDF and FTC. TDF was brought to market in 2001, before the creation of the Global Fund, and is only patented in 2 of 99 low-income countries. FTC was brought to market in 2003, after the creation of the Global Fund, and patents were reportedly filed in 45 countries of the 99 countries, including 38 countries in Africa.

Patents that Are Funded or Owned by Non-Profit Institutions

AIDS, Tuberculosis and Malaria are areas of global concern, and there is considerable public sector and philanthropic donor investment in innovation to treat these diseases. Patents that are a consequence of government or philanthropic support, or which are owned by non-profit institutions, including government or private sector research institutions and universities, would

be among those solicited for the licensing to the pool. In some cases, researchers and donors, including but not limited to governments, may have certain rights in inventions.

For example, among the AIDS drugs that are subject to various public interest clauses in the United States under the U.S. Bayh-Dole Act are patents on d4T, ddC, ddI, ritonavir, lopinavir, FTC, T-20 and abacavir.[7]

Relationship between the Patent Pool and Other Measures to Promote Competition and Effective Procurement

The proposed UNITAID Patent Pool would be one of several efforts to promote competition and efficient procurement. Brazil, Thailand and many other countries have achieved considerable cost savings through price negotiations that are strengthened by the possibility of issuing compulsory licenses. Several countries have directly used **TRIPS flexibilities** to limit patent coverage, issue compulsory licenses, or authorize parallel trade in medicines. The **Clinton Foundation HIV/AIDS Initiative,** with the support of UNITAID, has played a very important role in improving procurement practices, including **virtual pooling and joint price negotiations**. All of these efforts are very important and effective. The UNITAID patent pool would **complement** each of these efforts. The existence of the patent pool would likely influence competition and prices, even when the patent owners were not directly licensing patents to the pool, because the enhanced global norms for open competition would raise expectations that products would be priced closer to manufacturing costs. When patents are licensed to the pool, efforts like pooled procurement or price negotiations should be more effective than they would be in the absence of transparent open licenses for generic products. The challenge for this cost-benefit analysis is to assign a value to the patent pool in terms of increased competition, lower prices, and benefits in terms of innovation.

Costs of the Pool

As estimated and proposed by the UNITAID Secretariat, the initial start-up costs of the pool should total $1.5 million per year for three years, or $4.5 million. The $1.5 million budget is anticipated to be sufficient to pay for the hiring of at least two senior and two support staff and pay for office expenses, travel for the board, staff and advisory boards, as well as insurance, accounting, legal, consulting, and public relations services.

Benefits of the Patent Pool

7 For example, under 18 USC 202(c)(4), a U.S. Federal agency that funds research "shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: Provided, That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production."

For patent owners, a patent pool with widely accepted standardized licenses and good relationships with users of patents (generic suppliers), regulators, governments and donors can offer a cost-effective and rapid method of implementing open licensing of inventions that appropriately addresses such issues as the quality of licensed products, royalty rates and collection methods, and the management of intellectual property rights for improvements on licensed inventions, consistent with transparency and the rule of law.

For drug developers, access to the portfolio of patents in the pool can make it easier to develop new fixed dose combinations for other improvements in delivery methods, such as simplified dosing, heat stabilization of products, oral delivery of T-20, etc.

For patients, the patent pool can contribute to more competition and better products, particularly in the development of appropriate formulations such as triple FDCs, FDCs for Preventing Mother-to-Child Transmission (PMTCT), and pediatric formulations, as well as better prices and assurances regarding the quality of products. It will also help to ensure early entry of improved treatments into the market in developing countries.

For donors, the patent pool provides a mechanism to enhance the transparency of the patent landscape, enhance and expand the role of open licensing of inventions, and to increase competition, innovation, and to lower prices for products.

Brook Baker, of Health GAP and Northeastern University, estimates that open licensing of AIDS drugs through the patent pool could lower the prices of second line treatments by 50 percent (below originator prices) in low-income countries and by 70 percent in middle-income countries. (See attachment)

In sub-Saharan Africa alone, the WHO estimates that each year 2 percent of the more than 2 million patients receiving treatment will need to shift to second line treatments. Holding this rate steady, the number of patients requiring second line treatments will **increase** by more than 200,000 within five years.

Benefits and Contributions of the Patent Pool to Open Licensing

Originator prices and licensing strategies for second generation products are heterogeneous, and difficult to predict. Rather than present a single prediction, one can consider a range of possible scenarios, each based on a different set of assumptions regarding demand for second line/second generation products, originator prices and the estimated savings from open competition.

Each scenario presents the possible savings achieved by a patent pool in terms of a percentage. This percentage can be said to represent both the share of the products subject to open competition, as well as the impact of the pool in promoting competition by introducing open licensing norms in countries where patents exist.

In the most optimistic cases, the patent pool would be widely supported by donor and recipient governments, civil society, socially responsible investors and opinion leaders, and it would be decisive in making open licensing the norm for second line/second generation markets in low- and middle-income countries. In less optimistic cases, the patent pool would be less effective in promoting open licensing, particularly for middle-income countries. These calculations are not ideal and lack, for example, feedback between the role of open competition in middle income countries and the price savings in low-income countries. They do illustrate, however, the possible benefits of measures to strengthen competition, demonstrate the importance of such interventions, and justify the relatively modest funding requirements of a patent pool.

Several scenarios are presented below. Low-income countries are designated as Category 1, and middle-income countries are designated as Category 2.

Scenarios

Scenario 1					
Assumptions:			Cat. 1	Cat. 2	
Patients requiring second generation/second line treatments			**200,000**	**40,000**	
Innovator Price			**750**	**3,000**	
Generic Savings			**30%**	**70%**	
Savings Given Impact Factor	10%	25%	50%	75%	100%
Cat. 1	4,500,000	11,250,000	22,500,000	33,750,000	45,000,000
Cat. 2	8,400,000	21,000,000	42,000,000	63,000,000	84,000,000

Scenario 2					
Assumptions:			Cat. 1	Cat. 2	
Patients requiring second generation/second line treatments			**300,000**	**60,000**	
Innovator Price			**750**	**3,000**	
Generic Savings			**50%**	**70%**	
Savings Given Impact Factor	10%	25%	50%	75%	100%
Cat. 1	11,250,000	28,125,000	56,250,000	84,375,000	112,500,000
Cat. 2	12,600,000	31,500,000	63,000,000	94,500,000	126,000,000

Scenario 3					
Assumptions:			Cat. 1	Cat. 2	
Patients requiring second generation/second line treatments			**500,000**	**100,000**	
Innovator Price			**750**	**3,000**	
Generic Savings			**50%**	**87.5%**	
Savings Given Impact Factor	10%	25%	50%	75%	100%
Cat. 1	18,750,000	46,875,000	93,750,000	140,625,000	187,500,000
Cat. 2	26,250,000	65,625,000	131,250,000	196,875,000	262,500,000

Break-Even Analysis

Undiscounted savings:	Scenario 1	Scenario 2	Scenario 3
Cat 1	45,000,000	112,500,000	187,500,000
Cat 1 + Cat 2	129,000,000	238,500,000	450,000,000
The break even "impact" probability @ $1.5 million annual budget for patent pool			
Cat 1	3.33%	1.33%	.80%
Cat 1 + Cat 2	1.16%	0.63%	.3%

Concluding Summary and Comment

This analysis has looked at the costs and expected benefits of the proposed UNITAID patent pool. The costs of the pool are assumed at $1.5 million per year.

The quantified benefits of the pool include expected lower prices for second generation/second line products, as a consequence of a higher level of generic competition.

The most important assumptions that drive the results in this analysis are:

1. The expected originator prices and the savings from generic competition, and
2. The expected number of patients requiring access second generation/second line products.

Of these two assumptions, the most conservative assumption is in the number of patients that will require access to second generation/second line productions. Of the approximately two million patients today receiving treatment in sub-Saharan Africa, only an estimated one percent is reportedly receiving WHO defined second line treatments. This is far below the numbers of patients who receive second line treatments in Europe, the United States or Latin America.

Scenario 1 predicts only 200,000 patients in all low-income countries requiring treatment with second generation/second line products. **Scenario 3**, in theory the most aggressive, only assumes 500,000 patients requiring such treatments. Based purely on the rate of use of both second generation and second line treatments in the Europe and the United States, even the **Scenarios 3** figures may be low for the **Category 1** low-income countries.

The same can be said of the assumptions regarding patients in the **Category 2** countries. The WHO data suggests 92 thousand persons in Latin America alone are already receiving second line treatments, a figure that is only slightly lower than the 100,000 patients used in Scenario 3, which is the most optimistic in terms of estimated benefits. The relatively low numbers used in the scenarios above for both **Category 1** and **Category 2** are designed to reflect expected *additional demand* for second generation and second line products. However, clearly the benefits of open generic competition will flow also to the patients already using second line/second

generation products, so the estimated benefits are systematically underestimated for **Categories 1 and 2**, and particularly for **Category 2**.

The assumptions regarding originator prices are based upon recent prices by originators, before facing serious competition from generic manufacturers.[8] The estimated savings from competition are based upon data from the MSF surveys of ARV drug prices, recent data from Thailand and Brazil following the introduction of generic competition for second line/generation products, and estimates by several drug pricing experts.

The assumptions regarding originator prices, generic savings and demand for second line/generation products are used to calculate the raw, undiscounted benefits of open licensing. In the first three tables, these benefits are then considered at 10, 25, 50, 75 or 100 percent, to reflect the expected savings under different assumptions regarding the impact of the pool on outcomes.

A patent pool will be only one factor among several in determining outcomes. In the absence of such a pool, generic suppliers, treatment activists, procurement managers, and developing country governments have managed to implement generic competition to some extent for many important products. The "impact" of the pool is an assumption regarding the degree to which open competition is expanded by the existence and activities of a UNITAID patent pool. A 10, 25 or 50 percent impact factor would give the pool the relevant share of credit for expected savings from competition in the area of new products. By showing a range of possible impact factors, readers can consider several possible values.

In the table labeled "Break-Even Analysis," there is a calculation of the impact factor that would just break even with the estimated $1.5 million annual budget of the patent pool. This includes two rows of figures, one for **Category 1**-only savings, and the other for the combined value of **Category 1** and **Category 2** savings.

The most conservative approach is to consider only the expected the impact of the pool for **Scenario 1/Category 1**. Here, savings are only considered for low-income countries, in the most conservative assumptions regarding demand. For this combination, the pool would be justified if it has a combined impact of 3.3 percent on expected competition for second generation/second line products. Looking only at **Category 1** savings, the break-even impact would be 1.33 or .8 percent for Scenarios 2 and 3.

When one takes into account both **Category 1** and **Category 2** savings, the break-even impact figures are 1.16, .63 and .33 percent, respectively, for Scenarios 1, 2 and 3. In other words, if the pool only has a 1 percent impact on generic competition, it will pay for itself.

As noted in the introduction, the quantitative analysis presented above does not capture other possible benefits to be derived from the pool. There is no quantification of the benefits of increased competition and better management of patent portfolios in the development of better manufacturing processes, new fixed dose combinations (FDCs) or other improvements in delivery methods, such as simplified dosing, heat stabilization of products, oral delivery of

8 If this analysis was done in 2000, the originator prices would have been far higher -- $10,000 for the most common first line regime used today, for example.

injectable treatments, and the development of appropriate formulations such as triple FDCs, FDCs for Preventing Mother-to-Child Transmission (PMTCT), and pediatric formulations. These yet-to-be-quantified benefits are likely to be very large, and almost any success in this area would easily justify the entire start-up cost of the patent pool. *(The expected quantified benefits for innovation could be addressed in a subsequent analysis.)*

In terms of considering the proposal to establish the UNITAID patent policy, policy makers may find it useful to consider the 10 and 25 percent impact calculations from **Scenario 2**. These seem to require only modest expectations of the impact of a UNITAID patent pool on competition for second line/second generation products.

Low End of Scenario 2 Benefits

Savings Given Impact Factor	10%	25%
Cat. 1	11,250,000	28,125,000
Cat. 1 plus Cat. 2	33,850,000	59,625,000
Benefit-Cost Ratio		
Cat. 1	7.5	18.8
Cat. 1 plus Cat. 2	22.6	39.5